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Connecticut Medicine

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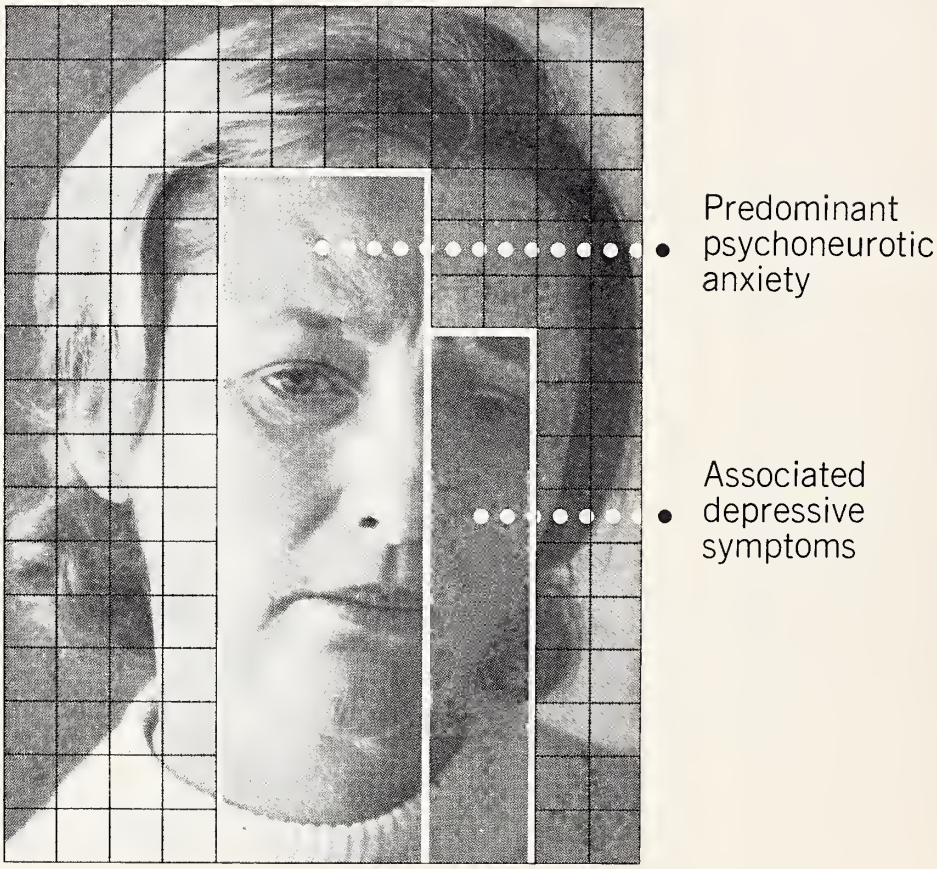
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Primary Therapy of Operable Breast Cancer

Ira S. Goldenberg, M.D.

Female breast cancer has been a surgical problem since the ancient Egyptians first described it. At that time the operative techniques were not quite as sophisticated as we would like to think they are today. The operation consisted of elevation of the breast with pincers and amputation with a red hot poker-type of instrument. Needless to say, the mortality and morbidity rates were rather high. I think modern surgery has minimized that problem somewhat, but not without a difference of opinion about the technique that should be utilized for a particular patient.

Breast surgeons have been very fortunate over the years in having a patron saint in St. Agatha. St. Agatha had unassailable piety and virtue and one of the Roman governors thwarted in attempts to seduce her, as punishment, amputated her breasts. Her martyrdom followed and since that time she has been considered our patron saint. It is very important to recognize that we need as much help as we can get in dealing with this particular problem of breast cancer.

The more modern era of breast surgery came with Angelo Nanonni who in the mid-1700's described a radical operative procedure for breast cancer very much as has been accepted through succeeding centuries. Halsted in 1890, unaware of his Italian predecessor, detailed a procedure he thought was rather unique with total excision of the breast, the underlying pectoralis muscles and the axillary lymph nodes. His original description interestingly enough, included a supraclavicular node dissection, something which he abandoned not long after his first description when he recognized how easy it was to enter the pleura and in that particular era, the management of such problems was extremely difficult. Radical mastectomy, then, for the last 80 years has been the accepted therapy for the treatment of female breast cancer.

There has been a great difference of opinion, however, regarding the best therapy for breast cancer over the last several decades. The End Results Evaluation Section of the National Cancer Institute has analyzed data from various parts of the world by therapeutic modality and has demonstrated the popularity of various techniques from one part of the world to another. For example, in Great Britain the majority of patients are treated by a combination of surgical intervention and radiotherapy. In Scandinavia, there are even more patients in this category while in the United States surgery alone is most often utilized. Yet, in each of these countries the 5-year survival data is not very much different from one modality of therapy to the next when one considers the entire spectrum of the disease. This sort of quantitative approach has caused many physicians to think that perhaps we don't owe radical mastectomy the sort of homage that has been paid it over the years as the only way of treating female breast cancer.

Another aspect that has perplexed many individuals who treat large numbers of patients is the "quality" of survival. In Connecticut data was compiled a few years ago in a group of women with radical mastectomies interviewed shortly after the operative procedure and again a year later. During these interviews attitudes toward the operation and the patient's surgeon as well as objective evaluations of such things as lymphedema of the arm and ability to perform a full range of arm motor activities were evaluated. This study demonstrated the common occurrence of arm lymphedema, the problems of motor function activity, and the patient's rather unhappy attitude about her operative procedure. This kind of qualitative data makes the surgeon uncomfortable in doing a radical mastectomy recognizing that there will be a certain number of problems that arise physiological, physical and psychological.

Professor Robert McWhirter must be given credit in the modern era for bringing to the attention of the medical world the problems of radical mastectomy and emphasizing that perhaps a lesser procedure is adequate in treating this disease. He advocated a total mastectomy followed by radical radiation therapy to include the regional lymph node drainage and the chest wall. His early experience utilized ortho-voltage radiotherapy which created many problems in so far as the local radiation effects were concerned. Later, with the advent of

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This paper is based on a talk given at a post-graduate symposium on "Current Concepts in Cancer Management," November 8 - 10, 1973 in New Haven. The symposium was sponsored by the Office of Regional Activities and Continuing Education and the Section of Medical Oncology, Yale University School of Medicine.

The symposium coordinator and editor for this article is Dr. John Marsh, Associate Professor of Medicine and Pharmacology, Yale University School of Medicine. The support of the Connecticut Division of the American Cancer Society is gratefully acknowledged.

better radiotherapeutic modalities, those problems disappeared and his 5-year survival data with total mastectomy and radiation therapy achieved pretty much the same kind of result as was noted earlier with radical mastectomy.

The pendulum over the last few years has swung even further to the ideas that Crile and others like him have been promulgating. In particular, Crile has suggested doing much less than a mastectomy. In fact, he advocates at this point, a wide local excision of the cancer leaving the breast intact as well as the regional lymph nodes and the underlying muscles. Some of his patients undergo radiation therapy, others do not. In a summation of TNM Stage I and II data from his own clinic local excision patients survived as well as patients treated by his colleagues with modified radical or total mastectomy. I think it very important to emphasize that Crile does not feel that this type of operative procedure is applicable to all patients but rather only to Stage I and Stage II lesions. This is a procedure for the early cancer. Further data from Washington University in St. Louis demonstrates that local excision of the cancer with post-operative radiation therapy resulted in a survival experience quantitatively much the same as radical mastectomy.

The essence of primary treatment of female breast cancer is to tailor the operation to the extent of the disease at the time of diagnosis. If, for example, there is a tumor limited to the breast, it is quite obvious that local excision with nothing further in the way of treatment would be quite adequate. Total mastectomy would be applicable to those tumors that one can consider multi-centric in origin. As one proceeds to more complicated involvement of breast and regional lymph nodes, it is obvious that more complicated procedures must also be necessary. The practical problem of this sort of reasoning, however, is obvious since there is no way at the present time to determine the total extent of the disease in the patient. In the unsophisticated past it was felt that physical examination alone was adequate to determine extent of disease, but how often we noted microscopic nodal involvement when no nodes were appreciated clinically. Is there distant metastatic disease already present at the time of the initial diagnosis? Radiographic examination of the patient picking out in particular those sties most likely to be involved with metastases may be inadequate. Total body bone scans have demonstrated that many patients who seem to have Stage I disease (by TNM clinical classification) already have osseous metastases present. It is obvious then that some patients will have an operative procedure unnecessarily radical for the extent of the disease present and other patients, by the same token, will have operative procedures totally inadequate for the amount of disease present, but unrecognized by the clinician. Hopefully, there will yet be developed some technique for determining the presence of malignancy at a remote site from the primary tumor so that the true picture of the patient and her cancer can be determined before any therapy is instituted.

This discussion does not stand as a recommendation for one form of primary therapy of breast cancer over another. What I hope to accomplish more than anything is to emphasize how little we understand about the mechanisms of the disease insofar as spread is concerned and suggest that thoughtful physicians will consider these inadequacies when planning therapy. I suspect strongly that breast cancer is a much more systemic disease from its outset than has been appreciated to the present time. It is quite possible that surgical therapy *per se* is really limited to the tip of the iceberg. Thoughtful physicians should be aware of the problems involved in various modalities of therapy and should try to plan for their patient, in our present state of ignorance about the disease, the best operative procedure or combination of procedures including radiation therapy. Perhaps the most important point of all is to follow the patient carefully after the initial therapy, recognizing the high potential for recurrence of disease at the local site or at a distance from the primary tumor. Early recognition of such spread can certainly allow institution of therapy earlier than if one waits for symptomatic problems to appear, at which time any therapy is probably not going to make too much difference to that particular patient and her survival experience.

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The Place of Hypophysectomy in the Management of Metastatic Breast Cancer

John C. VanGilder, M.D.

Since 1887, following Schinzinger's observation that younger females made older by oophorectomy would frequently have a regression of metastatic or primary breast cancer, alteration of the hormonal mileau of patients with breast cancer has assumed paramount importance in the handling of this disease. Approximately 60% of patients at some time will show evidence of metastasis from breast carcinoma following treatment of the primary malignancy and between 30-47% of these will respond to some type of simple endocrine manipulation, *i.e.*, oophorectomy, administration of estrogens, androgens, steroids and/or progesterone.

Major endocrine manipulation includes hypophysectomy or adrenalectomy and in this institution we have concentrated our efforts on hypophysectomy. The theoretical advantage of hypophysectomy compared to adrenalectomy is ablation of lactogenic and growth hormones, both of which have been demonstrated to exacerbate metastatic breast carcinoma in isolated clinical observations and in the experimental animal.

Review of the literature indicates that between 32-40% of non-selected patients show a remission greater than six months following hypophysectomy. Remission is defined as the calcification of lytic bone lesions, reduction in size of metastatic lesions by at least one-fourth without appearance of new lesions, or no further progression of developing metastasis. The average life expectancy in responders following hypophysectomy is 18-22 months (Table 1). Non-responders, by comparison, following hypophysectomy have a life expectancy of 4-7 months. The average duration of remission is between 12-18 months, there being considerable variation in the literature.

TABLE I

DURATION HYPOPHYSECTOMY RESPONSE

	Survival (Mos.)	*Remission (Mos.)*
Responders	18-22.7	12-18
Non-Responders	4.4-7	

With patient selection for hypophysectomy, considerable improvement of the aforementioned statistics can be obtained. The criteria for selection include age, interval between diagnosis and evidence of metastasis, previous response and duration of response following simple endocrine therapy, and organ system involved.

Age—Patients in the fourth and fifth decade and those who developed breast carcinoma more than four years following menopause have an increased remission frequency following hypophysectomy.

Interval between primary malignancy to metastasis—Patients with metastases appearing 2-3 years or more than 4 years after diagnosis of breast carcinoma have a somewhat longer duration of response to hypophysectomy than the average group.

Previous response to hormonal manipulation—If a patient shows objective remission of metastatic disease for more than 6 months following oophorectomy, the frequency of a similar remission is between 55-90% following hyphophysectomy, or 2-3 times the likelihood of the randomly selected patient. Post menopausal patients having either remission or exacerbation of metastatic lesions following administration of estrogens will similarly have an increased likelihood of remission with major endocrine manipulation.

Organ system involved—Metastatic deposits in certain organ systems respond to pituitary ablation better than others. Metastases to bone and lymph nodes have the best response; lung, subcutaneous tissue, skin, and pleura are intermediate; while the central nervous system and liver have the lowest response rate. The prognosis is better if only one system is involved, with a decreasing response rate with involvement of two or more systems.

Experience and development of hypophysectomy—The experience of the Yale Neurosurgical Group over 20 years in this and other institutions with hypophysectomy for breast carcinoma totals 394 patients (Table 2). The initial surgical approach was transcranial (168 patients) and the principal complication was 5% (9 patients) mortality. It should be remembered that many patients are severely debilitated by their metastatic disease and thus not optimal surgical risks. Visual impairment (3 patients),

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The symposium coordinator and editor for this article is Dr. John Marsh, Associate Professor of Medicine and Parhmacology, Yale University School of Medicine. The support of the Connecticut Division of the American Cancer Society is gratefully acknowledged.

TABLE II

HYPOPHYSECTOMY FOR BREAST CARCINOMA

394 PTS.	184 Responses (46.8%)
156 unselected patients	— 45 responses (29%)
238 selected patients	— 139 responses (57%)

increased neurological deficit (4 patients), and diabetes insipidus (22 patients or 12%) were also significant in this group.

In an effort to lower the mortality, a second group of 50 patients had stereotaxic placement of yttrium for hypophysectomy. The complications in this group included one operative death, 11 CSF fistulae, 9 episodes of diabetes insipidus (3 permanent), and 2 patients developed visual loss. Delayed complications appeared in 22 patients, of which CSF fistulae (9 patients) were the most prominent.

Stereotaxic cryohypophysectomy in 116 patients was associated with the lowest mortality (1 patient). However, development of CSF fistulae in 12 patients (3 requiring operative repair), and diabetes insipidus (8 permanent) were the major complications. Cryohypophysectomy has the disadvantage of a high incidence of incomplete pituitary gland ablation.

In the last 94 patients, which is our current group, the pituitary is surgically removed by the transethmoidal- or transseptal-transsphenoidal surgical approach. This procedure has the advantage of minimal surgery since it is not necessary to violate the intracranial cavity, low morbidity, and direct visualization of the pituitary gland for total removal Complications have included one postoperative death at three weeks from a pulmonary embolus, 14 patients with transient diabetes insipidus (3 permanent), meningitis (3 patients all responding to antibiotics), and 2 CSF fistulae requiring reoperation, the latter complication occurring early in the series. The average hospitalization is eight days, but the majority of patients are discharged at five days on replacement therapy of cortisone acetate 37.5 mgs, and thyroid extract 120 mgs per day.

In summary, hypophysectomy will result in a remission of a significant group of patients with metastatic breast carcinoma, enabling them to continue a functional existence for many months.

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Chemotherapy of Breast Cancer

Malcolm S. Mitchell, M.D.

Nonhormonal chemotherapy, with cytotoxic agents of a variety of classes, has proved to be of considerable importance in the management of patients with disseminated breast cancer. One striking general observation is that most of the agents that have been tried over the past few years have given almost the same response rate: 25 to 30%. The fairly uniform response rates, despite the use of drugs with dissimilar modes of action, provide evidence for what has come to be known somewhat vaguely as the "biology" of breast cancers, meaning that the nature of the disease in an individual patient instead of the drug determines whether the antitumor agent will be effective. If one chooses any one of the alkylating agents ("mustards"), such as cyclophosphamide (Cytoxan), chlorambucil (Leukeran) or melphalan (Alkeran), one can achieve a 30 to 35% response rate. Similarly, with antimetabolites such as 5-Fluorouracil (5-FU), or methotrexate or the vinca alkaloids vincristine or vinblastine, the rate of response is very much the same, 20 to 30%, depending upon the specific study examined. However, the recently introduced agent adriamycin (Doxorubicin), leads to responses in 40% of patients. The apparently higher response rate of adriamycin is very encouraging, and suggests that one need not pessimistically blame the "biology" of the tumor for suboptimal responses in the past but simply the lack of chemical

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This paper is based on a talk given at a post-graduate symposium on "Current Concepts in Cancer Management," November 8-10, 1973 in New Haven. The symposium was sponsored by the Office of Regional Activities and Continuing Education and the Section of Medical Oncology, Yale University School of Medicine.

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agents with sufficient tumoricidal ability, a situation that may now soon be remedied.

One means of improving the quality and duration of remission is through the use of combinations of agents that are effective but suboptimal individually. A regimen composed of 5 effective agents, 5-FU, methotrexate, vincristine, cyclophosphamide and prednisone, has been reported to give from 60 to 80% responses in group trials. Although published documentation has never been provided, the physician who devised the regimen has reported a response rate of 90% among his own patients. It is entirely possible that only two or three of the five agents may be required for this doubled response rate, a point that is now being clarified in cooperative group trials throughout the country. Two simpler combinations deserve mentions since they involve adriamycin. Adriamycin and vincristine, which have very different sorts of toxicity on the bone marrow elements and peripheral nerves, respectively, have been used at maximum effective doses for each in combination by Bonadonna and his coworkers in Italy, who have reported a 60 to 70% response rate with a 6-month median duration of remission. Adriamycin and Cytoxan, which have similar toxicities, nevertheless have produced a synergistic antitumor effect in combination, which appears to be at least equal to that of adriamycin-vincristine. It is probable that until a preeminently effective single agent is found, one or another of such combinations as these will be used to achieve a better response rate in patients at risk, with a better quality of response—i.e., a return to complete functional competence. I would be remiss in failing to emphasize that many of our patients have returned to full-time job after sustaining a remission with chemotherapy, and several have appointments to receive chemotherapy late on Friday or occasionally on a Saturday morning in order to avoid missing work too frequently. We are not speaking here about an objective regression of disease that is measurable only by the attending physician.

Osseous and visceral disease respond to chemotherapy, often regressing nearly completely, but soft tissue disease is most amenable to therapy. The variability with which osseous metastases respond to hormonal manipulations alone suggests that chemotherapy might be added or substituted for hormonal therapy in this situation. Early chemotherapy as an adjunct or "adjuvant" to surgery, is gaining in popularity among surgeons as its effectiveness has become suggested strongly in cooperative group trials. Melphalan has been effective even in low doses and short durations of therapy in the surgical patient with a high risk of recurrence (with positive axillary lymph nodes), making it imperative to try more effective agents and regimens in the future. A combination of agents effective in disseminated disease is entirely logical. The use of a highly effective single agent such as adriamycin is also logical, although its cumulative cardiac myotoxicity limits the duration of the regimen. Alopecia, which may occur with Cytoxan, adriamycin and several other agents, should not dissuade the physician from using them in the asymptomatic patient, since the cosmetic problem is usually psychologically tolerable to the patient, and in any event the hair regrows, often during continued therapy.

Adjunctive immunotherapy, with nonspecific immunological stimulants such as BCG or Corynebacterium parvum, does not have as strong an experimental support as adjunctive chemotherapy, but it seems inevitable that studies of immunological adjuvants in the immediately post-surgical breast cancer patient will be performed in the near future. Chemotherapy, which could kill residual tumor cells, makes more sense initially, but there is nothing to exclude sequential chemotherapy and immunotherapy, with the latter intended to stimulate the host's own immunity to seek out and destroy the final tumor cells remaining after chemotherapy.

In summary, chemotherapy of breast cancer has greatly improved the prognosis in this disease, permitting patients with disseminated disease to lead nearly normal lives, occasionally for years. Programs using chemotherapy much earlier in the disease, perhaps immediately after surgery or in addition to hormonal manipulations, are likely to yield even better long term results than the highly compartmentalized sequential therapy in current practice, which reserves chemotherapy only for patients "irremediable" by other forms of treatment. Cooperation among surgeons, radiotherapists and medical oncologists combining approaches to the disease makes the near future of therapy of this type of cancer very promising.

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Colonoscopy—Preliminary Review of Surgical Applications

Bernard S. Shapiro, M.D. and John M. Hoffer, M.D.

The colon is one of the most common organs that the surgeon is called upon to diagnose and treat. Heretofore, the diagnostic tools at our command have been limited to the sigmoidoscope and the barium enema. Attempts have been made in the past to extend the range of the rigid sigmoidoscope, but these attempts have been limited by inability to pass the longer scope in many patients. The limitations of the barium enema are well known to anyone with experience in handling patients with colonic pathology. The recent advent of colonic cytology has added another tool to our armamentarium, but again with its own limitations. The advent of the flexible fiberoptic colonoscope has enabled us to expand our ability to diagnose and treat patients with colonic pathology even further. This paper is a summary of the experience of one private surgical practice with a 100 mm. length fiberoptic colonoscope.

Technique

The examination is done as an out-patient in our office as well as in hospital. Routine examinations as follow-ups are all done as out-patients. Patients for polypectomy or who are in the hospital for other reasons are done as in-patients. The preparation is the same. Clear liquids only are allowed on the day prior to the exam and 45 to 60 ccs. of castor oil are administered on that afternoon. Enemas until clear are given on the morning of the examination. Out-patients are premedicated with from 5 to 10 mgs. of Valium given intravenously just prior to the start of the procedure and in-patients are given a combination of Demerol and Seconal approximately one hour prior to their examination if polypectomy is anticipated. Early in our experience, the examinations were done with flouroscopic control, but as facility in passage was obtained this was abandoned and a standard examination room is now used. The patient is placed in the left lateral position, the digital-rectal examination is done and the instrument is inserted and advanced under direct vision.

Biopsies are taken with an alligator forceps through the operating channel of the colonoscope. Photography is done by a previously adapted camera. Colonic cytologies are done by retrieval and examination of irrigation fluid. Polypectomies are done using a snare cautery technique. We make our own snares by using a braided conductive wire which we pass through a polyethylene cannula prior to inserting the cannula through the operating channel of the instrument. Portable x-ray examinations are done when necessary to document location of the tip of the endoscope.

Results

Seventy-one patients have been colonoscoped in the past ten months. Eighteen polypectomies have been done on an additional fifteen patients. Two gastric polyps have been removed in conjunction with our gastroenterologists after they have positioned the instrument and visualized the polyp. There have been no complications. Two polyps were unable to be retrieved. Four of the eighty-nine patients were examined through colostomy stomas and the ascending colon was easily reached in both. In four patients, the examination was purposely discontinued because of pain. Two of these patients had resolving diverticulitis but the area in question was reached and the diagnosis of inflammatory disease vs. carcinoma was resolved; one patient had an early acute onset of ulcerative colitis and the examination was discontinued because of the fear of perforation; and the fourth patient had a clinical diagnosis of diverticulitis but a polypoid mass was seen in addition and on that basis surgical intervention was recommended. Of the remaining eighty-one patients, there were about seven patients in whom the sigmoid descending colon junction was unable to be negotiated. However, in the last fifty-some-odd patients, only in one or two instances was the operator unable to insert the instrument into the transverse colon. Of the polypectomies, one polyp was at the hepatic flexure beyond the reach of the scope but within vision. This patient had one year previously suffered a myocardial infarct in the post-operative period following a sleeve resection of the descending colon. Because of her poor operative risk status, this polyp, which was found on a routine follow-up examination, was endoscopically snared. Because it was several cms. beyond the end of the scope, it was unable to be retrieved. One five year old child underwent removal of a juvenile lesion of the descending colon and this polyp was also lost and unable to be retrieved with removal of the instrument. Both these patients will be followed

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closely. One seventeen year old female with rectal bleeding had three polyps removed from her descending colon. These all turned out to be juvenile in nature. Another patient had two polyps in the descending colon. The remainder of the patients had one polyp each in the transverse, descending or sigmoid colon. Most of these were adenomatous but there were a few villous papillomas found on histologic examination and one invasive cancer.

Discussion

The availability of an instrument which allows for direct inspection of the colonic lumen, for photography of this area, for biopsy of suspicious lesions, and for removal of polyps without major abdominal surgery must of necessity have an effect on what is recommended for our patients with colonic lesions. In our brief experience, fifteen patients were spared laparotomy and polypectomy, an operative procedure with a mortality rate of approximately 1% and a morbidity rate of up to 20%. There were also two patients who were spared gastrotomy for removal of their gastric polypoid lesions. The ability to see, biopsy and excise polyps should make the operation of colotomy and polypectomy almost obsolete.

Surgical intervention in the subsiding phase of diverticulitis is avoided by most surgeons. Yet frequently because of the inability to distinguish that lesion from a carcinoma with conventional diagnostic maneuvers, patients are explored at an earlier date than optimum. In three patients we have visualized the area in question, saw no mucosal lesion other than edema and have felt perfectly safe in waiting for complete subsidence of the inflammatory reaction prior to operation. In a fourth patient, a mucosal lesion was seen and operative intervention was advised. One theoretical use for colonoscopy in diverticulitis patients would involve direct injection of contrast material into the surgical area to clearly delineate any possible sinus tract. But the use of the colonoscope in acute diverticulitis must be done with great care and we have waited several weeks for subsidence of the acute reaction prior to the examination.

Often after surgical resection of colonic neoplasms, follow-up barium enema examination will reveal anastomotic irregularities which raise the question of recurrent tumor. We have been able in several cases to visualize the suture line and biopsy mucosal tags.

Finally, in our experience, we feel that observation of the colonic mucosa in association with barium enema would certainly allow closer follow-up of our cancer patients and earlier detection of small lesions.

It is interesting to speculate on other indications for colonoscopy which we have not yet had the opportunity to face. Would the sigmoid volvulus which does not respond to sigmoidoscopy be able to be reduced with the colonoscope? Would the progress of inflammatory lesions of the colon be better determined under direct vision? The answers to these questions remain to be discovered. Speculation has been made regarding the use of the colonoscope to diagnose the site of massive lower GI bleeding. We would doubt that this would be a feasible procedure because of the quality of preparation needed for an acute examination, and during the acute bleeding episode it is almost impossible to clean the colon sufficiently.

Summary

A presentation has been made of the application of fiberoptic colonoscopy in one surgical practice. Eighty-nine patients have been colonoscoped. Eighteen polypectomies have been done in fifteen patients. There have been no complications. Other diagnostic applications of the procedure have been presented and some theoretical applications have been discussed.

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Cold Injury: A Review of Current Theories and their Application to Treatment

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Cold Injury

We plan today to review some of the thinking on cold injury since the 1940's with emphasis on certain pathologic findings or experimental studies which we think are pertinent to present work or has influenced the current treatment. Major emphasis will be placed on current work in Cryo-biology which is being carried out on a cellular level and which gives better understanding of the differences between the classic frostbite or injuries involving freezing and the cold wet injuries at above freezing levels, commonly called immersion foot or trench foot.

In World War II, because of lack of command awareness, American physicians had a large experience in cold injuries, and I quote from Simeone's report from the surgical volumes of the History of the United States Medical Department in World War II. "In all cold injuries the pathologic changes are essentially similar. Such differences that exist are explained by differences in duration and severity of exposure." He then refers to the work of Freidman, who studied pathologic findings of some 14 specimens; larger studies not being available as most frostbite or cold injuries do not yield pathologic specimens.

There are several points I would like to quote:

1. "There is proliferation of adventitial cells in the capillaries and smaller vessels.
2. Engorgement of the vascular tree with erythrocytic agglutinative thrombi, poor in fibrin of the type seen in stagnant blood.
3. Mural hemorrhage in both plugged and patent vessels. Many vessels dilated, but others showing vasal constriction."

Dr. Simeone summarizes the understanding of the mechanisms of the process during the period of the 2nd World War, when he states:

> "Most changes observed in this study are regarded as secondary to vascular occlusion, but it was also thought that structures rich in lipoids, especially adipose tissues and myelinated nerve fibers might sustain a possible direct thermal effect from cold trauma, and in summary notes that a satisfactory treatment for cold injuries has never been devised and few therapeutic advances were made during World War II."

During the 1950's, Bellman, Adams-Ray and others did thorough studies of cold injuries in rabbit ears, showing that rapid thawing of tissue in frostbite yielded less necrotic tissue than slow thawing. It was not clear then and it still isn't whether this is strictly a matter of time x temperature relationship or whether some other specific mechanism was involved. In addition to this portion of the work, they studied the specimens very carefully with microangiography. Many of the changes were non-specific and they could not differentiate by observing the vascular response, which tissues would go on to become necrotic and which would not.

We have now passed through 2 phases of scientific study in cold injury. One is that of the pathology of the fixed specimen. The second is that of the functional disturbance as followed by microangiography.

Since the 1960's continuing into the present, there has developed a large body of work on cellular and subcellular mechanisms of cold injury.

Current experimental work in the field of Cryobiology separates readily into 2 groups. One being those working at temperatures that are 0° C or below with actual freezing, i.e., ice formation. The other group is studying cold injuries at temperatures above freezing and in which there is no ice being formed.

In the first group, that is at temperatures at 0 or below, if freezing is rapid, as when the hand touches a super-cooled metal or a highly volatile liquid at sub-zero temperatures, there is intra and extra cellular crystal formation and rapid disruption of the cell membrane, primarily on a mechanical basis. In most frostbite, however, freezing is a slow process and extracellular ice crystals are formed. It is generally agreed that this results in the extracellular fluid becoming hypertonic in relation to the intracellular fluid and there are several theories as to how this injures the cell. One group has demonstrated that the injury is related to the volume of water lost, rather than the concentration

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and that when approximately 1/3 of the cell water has been lost, injury occurs. This injury, according to Merriman and Baker and others, is related to osmotic stress created when the cell resists the diminution in cell volume which accompanies water removal.

Litvan, however, and others in his group feel that this is a process of desorption and redistribution which results in a cellular dehydration and denaturization of protoplasmic protein.

These are two theories as to the mechanisms of injury with freezing. Even more perplexing is the cause of injury by cold at temperatures well above freezing. For many years it was accepted that immersion foot and trench foot were simply the result of ischemia caused by vasospasm and stasis.

There is now a considerable body of evidence, however, that cold itself has a damaging effect on the cell. Lyons, in his paper on *Phase transitions and control of cellular metabolism at low Temperatures,* postulates that there is a transition from a liquid crystalline state to a solid gel state in the lipid portion of the subcellular membranes at critical temperatures and that these phase changes disrupt enzymatic activity and metabolism which ultimately leads to the observed injury and malfunction.

The basis of his argument is first that it has been known for many years that the rate of metabolic processes is related to temperature and this can be expressed in a linear fashion. In homeothermic animals, however, those animals which maintain their body temperatures as humans or mammals do within a strict range, at a point well above freezing there is a break in the linear nature of the metabolic processes in their relationship to temperature. This break comes experimentally between 22 and 24 degrees centigrade. If one relates these experimental temperatures to papers reporting survival rates and treatment of individuals who have accidentally become hypothermic, one finds that below the critical core temperature of 24 degrees centigrade, there are rarely survivals.

These studies have progressed to a level of subcellular membranes and even down to molecular structures, and have increased our understanding of the processes. But what significance do they have for our patients?

First, there is total agreement that cold injuries can usually be prevented and cannot be cured. If the injury is primarily on a cellular level, which it appears to be rather than primarily on a level of tissue and organ malfunction, we surgeons are very limited as to what tools we have available.

Sympathectomy has a place in treatment of cold injuries, but many would agree that it is only when there is evidence of increased sympathetic tone, and this usually becomes clear only many weeks post injury. This appears to be more frequent in cold injuries without freezing, that is, immersion foot or trench foot.

Rapid warming is the basis of most current treatment and this should be carried out between 100-108°F. This magic number gives one the maximum temperature without causing injury from burn, which is a serious possibility if rewarming is carried out too enthusiastically.

The use of Heparin does not appear helpful. The clots which occur in cold injury are usually secondary to stasis with aggregation of cells and little fibrin and are associated as well with changes in the vessel walls themselves, which probably in part at least, explain the poor response. Dextran, and probably more importantly, hydration of the patient, making maximum use of the circulation that is present, appears rational, and judiciously used should not add to the edema. Physio-therapy, whirlpool, skin care, as in the treatment of any extensive trauma of the extremities plus judicious use of antibiotics where indicated and debridement are useful. In other words, good, basic, non-specific surgical care seems to be the only tool available to us.

In summary then I would have to note, as did Dr. Simeone, that a satisfactory treatment for cold injury has never been devised and few therapeutic advances have been made, but some greater understanding of the mechanisms involved has been achieved.

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CURRENT TRENDS

NOMENCLATURE OF ANTIGENS ASSOCIATED WITH VIRAL HEPATITIS TYPE B

by

Committee on Viral Hepatitis* of
the National Research Council—National Academy of Sciences

In April 1972, the Committee on Viral Hepatitis of the National Research Council employed, in its first publication *(1)*, the descriptive terms HB Ag and HB Ab for the antigen and antibody associated with viral hepatitis type B. Since then, growing evidence of the complexity of the antigen has highlighted the need to modify this nomenclature. It has been clearly established that the 42-nm structure now known as the Dane particle and the 20-nm spherical and filamentous particles are associated with viral hepatitis type B. The Dane particle consists of a core and an outer surface component, each having specific antigenic properties. The surface component is antigenically similar to the 20-nm particles. The 20-nm particles appear to be formed as the result of over-production of the surface component of the Dane particle. In addition, it has been established that this surface antigen manifests a group-specific determinant, a, and subtype-specific determinants, d or y, and w or r.

In view of these circumstances and in expectation of continuing revelations in this field, the Committee believes that scientific communication would be greatly enhanced by the acceptance of a standard nomenclature adaptable to newly discovered antigens, antibodies, or viruses. We therefore suggest that consideration be given the following system of nomenclature.

HB$_s$ Ag	The hepatitis B antigen found on the surface of the Dane particle and on the unattached 20-nm particles.
HB$_c$ Ag	The hepatitis B antigen found within the core of the Dane particle.
Dane particle	A current term for the 42-nm particle containing HB$_c$ Ag in its core and HB$_s$ Ag on its surface.
HBV	Reserved for hepatitis B virus. The Dane particle may turn out to be HBV.
HB$_s$ Ag/adr	Hepatitis B surface antigen manifesting the group-specific determinant, a, and subtype-specific determinants, d and r. All recognized subtypes are to be indicated to the right of the slash.
anti-HB$_s$	Antibody to hepatitis B surface antigen. If the subtypic reactivity is known, the appropriate antigenic determinants are to be indicated to the right of a slash.
anti-HB$_c$	Antibody to hepatitis B core antigen. If more than one core antigen is discovered, the corresponding antigens can be indicated.

The present use of HB Ab in designating the antibody to hepatitis B antigen should be abandoned.

Reference

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H.E.W., Public Health Service, Atlanta, Ga., January 26, 1974.

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Gonorrhea

Recommended Treatment Schedules, 1974
Center for Disease Control

The following recommendations were established by the Venereal Disease Control Advisory Committee after deliberation with therapy consultants†.*

UNCOMPLICATED GONOCOCCAL INFECTIONS IN MEN AND WOMEN

Drug Regimen of Choice

Aqueous procaine penicillin G (APPG) 4.8 million units intramuscularly divided into at least 2 doses and injected at different sites at one visit, together with 1 gm of probenecid by mouth just before the injections.

Alternative Regimens

A. Patients in whom oral therapy is preferred: Ampicillin 3.5 gm by mouth, together with 1 gm probenecid by mouth administered at the same time. There is evidence that this regimen may be slightly less effective than the recommended APPG regimen.

B. Patients who are allergic to the penicillins or probenecid (i.e. allergy to penicillin, ampicillin, probenecid, or previous anaphylactic reaction):
   1. Tetracycline hydrochloride, 1.5 gm initially by mouth, followed by 0.5 gm by mouth 4 times per day for 4 days (total dosage 9.5 gm). Other tetracyclines are not more effective than tetracycline hydrochloride. All tetracyclines are ineffective as single-dose therapy.
   2. Spectinomycin hydrochloride, 2 gm intramuscularly in 1 injection.

Treatment of Sexual Partners

Men and women with known recent exposure to gonorrhea should receive the same treatment as those known to have gonorrhea. Male sex partners of persons with gonorrhea must be examined and treated because of the high prevalence of nonsymptomatic urethral gonococcal infection in such men.

Follow-up

Follow-up urethral and other appropriate cultures should be obtained from men, and cervical, anal, and other appropriate cultures should be obtained from women, 7 to 14 days after completion of treatment.

Treatment Failures

Most recurrent infection after treatment with the recommended schedules is due to reinfection. True treatment failure after therapy with penicillin, ampicillin, or tetracycline should be treated with 2 gm of spectinomycin intramuscularly.

Postgonococcal Urethritis

Tetracycline 0.5 gm 4 times a day by mouth, for at least 7 days.

Pharyngeal Infection

Pharyngeal gonococcal infections may be more difficult to treat than anogenital gonorrhea. Post-treatment cultures are essential follow-up for pharyngeal infection. The schedules of ampicillin and spectinomycin recommended for anogenital gonorrhea are ineffective in pharyngeal gonorrhea. Patients whose infection is not eradicated after treatment with 4.8 million units of APPG plus 1 gm of probenecid may be treated with 9.5 gm of tetracycline in the dosage schedule outlined above (Alternative Regimens).

Syphilis

All patients with gonorrhea should have a serologic test for syphilis at the time of diagnosis. Seronegative patients without clinical signs of syphilis who are receiving the recommended parenteral penicillin schedule need not have followup serologic tests for syphilis. Patients treated with ampicillin, spectinomycin, or tetracycline should have a follow-up serologic test after 3 months to detect inadequately treated syphilis.

Patients with gonorrhea who also have syphilis should be given additional treatment appropriate to the stage of syphilis.

Not Recommended

Although long-acting forms of penicillin (such as benzathine penicillin G) are effective in syphilotherapy, they have **NO** place in the treatment of gonorrhea. Oral penicillin preparations such as penicillin V are not recommended for the treatment of gonococcal infection.

Note: Physicians are cautioned to use no less than the recommended dosages of antibiotics.

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TREATMENT OF UNCOMPLICATED GONORRHEA IN PREGNANT PATIENTS

A. For women who are not allergic to penicillin: Use the regimens of APPG plus probenecid or use ampicillin plus probenecid as defined above.

B. For pregnant patients who are allergic to penicillins (Note: there are several possible alternative regimens, each of which has potential disadvantages):

1. Erythromycin, 1.5 gm orally, followed by 0.5 gm 4 times a day for 4 days for a total of 9.5 gm. This regimen is safe for mother and fetus, but its efficacy has not been established. Erythromycin estolate should not be used in patients with underlying liver disease.
2. Cefazolin, 2 gm intramuscularly, with 1 gm of probenecid. Because of the possibility of cross-allergenicity between penicillins and cephalosporins, this regimen should not be used in patients with a history of penicillin anaphylaxis.
3. Spectinomycin, 2 gm intramuscularly, is an effective dose, but safety for the fetus has not been established.

Contraindicated

Tetracycline should not be used for uncomplicated gonococcal infection in pregnant women because of potential toxic effects for mother and fetus.

ACUTE SALPINGITIS (PELVIC INFLAMMATORY DISEASE)

The diagnosis of acute salpingitis should be considered in women with acute lower abdominal pain and adnexal tenderness on pelvic examination. Since there are no completely reliable clinical criteria on which to distinguish gonococcal from nongonococcal salpingitis, endocervical cultures for *Neisseria gonorrhoeae* are essential in such patients. Therapy, however, should be initiated immediately, without waiting for the results of the cultures.

A. *Hospitalization.* It should be strongly considered for women with suspected salpingitis in these situations:

1. Uncertain diagnosis, where surgical emergencies must be excluded
2. Suspicion of pelvic abscess
3. Pregnant patients with salpingitis
4. Inability of the patient to follow an outpatient regimen of oral medication, especially because of nausea and vomiting
5. Failure to respond to outpatient therapy

B. *Antimicrobial Agents.* Controlled studies of the treatment of acute salpingitis are not available. Initial management must **AT LEAST** be adequate for gonococcal salpingitis. These regimens are known to be adequate for the treatment of gonococcal salpingitis:

1. Outpatients
   a. 1.5 gm tetracycline hydrochloride given as a single oral loading dose, followed by 500 mg taken orally 4 times a day for 10 days.
   b. APPG 4.8 million units intramuscularly, divided into at least 2 doses and injected at different sites at one visit **OR** 3.5 gm of oral ampicillin. One gm of oral probenecid is given along with either penicillin or ampicillin, and both are followed by 500 mg of ampicillin taken orally 4 times a day for 10 days.
2. Hospitalized patients
   a. Aqueous crystalline penicillin G 20 million units given intravenously each day until clear-cut improvement occurs, followed by 500 mg of ampicillin taken orally 4 times a day to complete 10 days of therapy. The need for additional or alternative antibiotics for the treatment of nongonococcal salpingitis requires further study. Since it is impossible to distinguish gonococcal from nongonococcal salpingitis clinically, many physicians also use an aminoglycoside in addition to penicillin and/or antibiotics which are effective against *Bacteroides fragilis* as initial therapy.
   b. Tetracycline hydrochloride 500 mg, given intravenously 4 times a day until improvement occurs, followed by 500 mg taken orally 4 times a day to complete 10 days of therapy. This regimen should not be used for pregnant women or for patients with renal failure.
3. Failure to improve on the recommended regimens does not necessarily indicate the need for stepwise additional antibiotics, but requires reassessment of the possibility of other

diagnoses and of the specific microbial etiology.

C. The effect of the removal of an intrauterine device on the response of acute salpingitis to antimicrobial therapy and on the risk of recurrent salpingitis requires further study.

D. **Adequate treatment of women with acute gonococcal salpingitis must include examination and appropriate treatment of their male sex partners because of the high prevalence of nonsymptomatic urethral gonococcal infection in such men. Failure to treat male sex partners is a major cause of recurrent gonococcal salpingitis.**

E. Follow-up of patients with acute salpingitis is essential. All patients should receive repeat pelvic examinations and cultures for *N. gonorrhoeae* after treatment.

DISSEMINATED GONOCOCCAL INFECTION

A. Equally effective treatment schedules in the arthritis-dermatitis syndrome include:
   1. Aqueous crystalline penicillin G, 10 million units intravenously per day for 3 days or until there is significant clinical improvement. This may be followed with ampicillin, 500 mg 4 times a day orally to complete 7 days of antibiotic treatment.
   2. Ampicillin, 3.5 gm orally, plus probenecid 1 gm, followed by ampicillin, 500 mg 4 times a day orally for at least 7 days.

B. In penicillin- and/or probenecid-allergic patients:
   1. Tetracycline 1.5 gm orally followed by 500 mg 4 times a day orally for at least 7 days. Tetracycline should not be used for complicated gonococcal infection in pregnant women because of potential toxic effects for mother and fetus.
   2. Erythromycin 0.5 gm intravenously every 6 hours for at least 3 days.

C. Additional measures
   1. Hospitalization is indicated in patients who are unreliable, have uncertain diagnosis, or have purulent joint effusions or other complications.
   2. Immobilization of the affected joint(s) appears helpful. Repeated aspirations and saline irrigations appear beneficial, but controlled studies of these procedures have not been performed. Open drainage of joints other than the hip is now generally discouraged in patients with gonococcal arthritis.
   3. Intra-articular injection of penicillin is unnecessary, since penicillin levels in the synovial fluid of inflamed joints approximate serum levels; furthermore, intra-articular injection per se may produce a toxic synovitis.

D. Meningitis and endocarditis due to the gonococcus require high-dose intravenous penicillin therapy (at least 10 million units per day) for longer periods: usually at least 10 days for meningitis and 3-4 weeks for endocarditis.

GONOCOCCAL INFECTION IN PEDIATRIC PATIENTS

Pediatric patients encompass those from birth to adolescence. When a child is postpubertal and/or over 100 pounds, he or she should be treated with dosage regimens as defined above for adults.

The efficacy of therapeutic regimens for uncomplicated and complicated gonococcal infections of childhood is unproven at present.

With gonococcal infection in children, the possibility of child abuse must be considered.

Prevention of Neonatal Infection

All pregnant women should have endocervical cultures examined for gonococci as an integral part of prenatal care.

Prevention of Gonococcal Ophthalmia

A. One percent silver nitrate (do not irrigate with saline, as this may reduce efficacy).

B. Ophthalmic ointments containing tetracycline, erythromyclin, or neomycin are also probably effective.

C. **Not Recommended:** Bacitracin ointment (not effective) and penicillin drops (sensitizing).

Management of Infants Born to Mothers With Gonococcal Infection

Orogastric and rectal cultures should be taken from all patients. Blood cultures should be taken if septicemia is suspected. Aqueous crystalline penicillin G, 50,000 units/kg/day should be administered in 2 daily doses intravenously if cultures or Gram-stained smears reveal gonococci. The duration of therapy should be determined by clinical response. In suspected septicemia, an aminoglycoside should also be given.

Neonatal Disease

A. Gonococcal ophthalmia: Patient should be hospitalized. Antimicrobial agents: Aqueous crystalline penicillin G 50,000 units/kg/day in 2 or 3 doses intravenously for 7 days **PLUS** frequent saline irrigations and instillation of penicillin, tetracycline, or chloramphenicol eyedrops.

B. Complicated infection: Arthritis and septicemia should be treated by hospitalization and administration of aqueous crustalline penicillin G 75,000-100,000 units/kg/day in 4 doses or pro-

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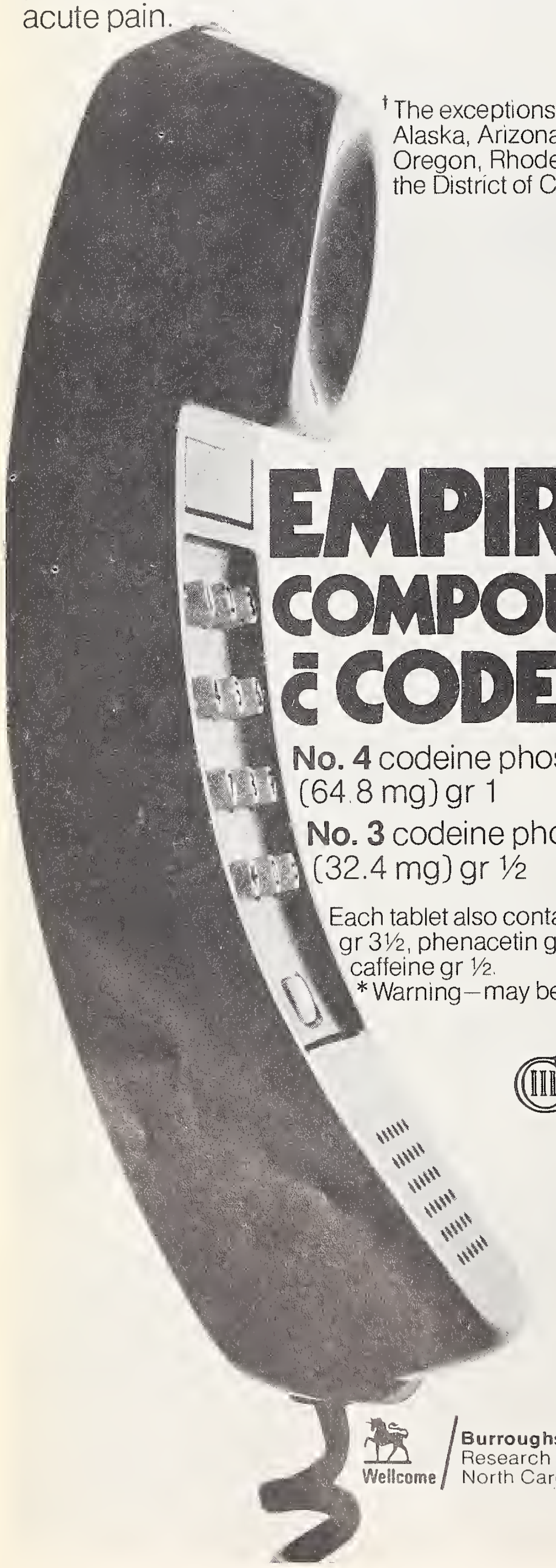

† The exceptions: Alaska, Arizona, Maine, Oregon, Rhode Island, and the District of Columbia.

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No. 4 codeine phosphate* (64.8 mg) gr 1

No. 3 codeine phosphate* (32.4 mg) gr ½

Each tablet also contains aspirin gr 3½, phenacetin gr 2½, caffeine gr ½.
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caine penicillin G 75,000-100,000 units/kg/day in 2 doses for 7 days. Meningitis should be treated with aqueous crystalline penicillin G 100,000 units/kg/day, divided into 2 or 3 intravenous doses a day and continued for at least 10 days.

Childhood Disease

Gonococcal ophthalmia should be treated with hospitalization and by the administration of aqueous crystalline penicillin G intravenously 75,000-100,000 units/kg/day in 4 doses or procaine penicillin G intramuscularly 75,000-100,000 units/kg/day in 2 doses for 7 days **PLUS** saline irrigations and instillation of penicillin, tetracycline, or chloramphenicol eyedrops. Topical antibiotics **alone** are **NOT** recommended in therapy of gonococcal ophthalmitis. The source of the infection must be identified.

Uncomplicated vulvovaginitis and urethritis usually do not require hospitalization. Both may be treated at one visit with APPG 75,000-100,000 units/kg intramuscularly and probenecid 25 mg/kg by mouth. Topical and systemic estrogen therapy are of no benefit in vulvovaginitis. All patients should have follow-up cultures, and the source of infection should be identified, examined, and treated.

Infection complicated by peritonitis or arthritis should be treated by hospitalization and administration of aqueous crystalline penicillin G intravenously 75,000-100,000 units/dg/day in 4 doses or procaine penicillin G 75,000-100,000 units/kg/day intramuscularly in 2 doses for 7 days.

Treatment of patients with allergy to penicillin: Patients under 6 years of age should be treated with erythromycin 40 mg/kg/day in 4 doses by mouth for 7 days for uncomplicated disease. Complicated disease should be treated with cephalothin 60-80 mg/kg/day in 4 doses intravenously for 7 days. Patients older than 6 may be treated with an oral regimen of tetracycline 25 mg/kg as an initial dose followed by 40-60 mg/kg/day in 4 doses for 7 days or an intravenous regimen of tetracycline 15-20 mg/kg/day in 4 doses for 7 days.

H.E.W., Public Health Service, Atlanta, Ga., October 5, 1974.

The President's Page

For over a century the matter of introducing into the public school system courses on Health Education has been under discussion. Dr. T.S. Lambert in a book titled "Hygienic Physiology," written in 1852, posed the question: "Why should Physiology be introduced into common schools?" He answers the question by saying, "If for no other reason, that no one may disgrace his intelligence by asking the question."

We bend our efforts toward upgrading the quality of medical care and toward making medical care available to all those who need it. But we neglect to educate people as to how to maintain their good health and how to recognize early the approach of ill-health. If we wish people to take advantage of available health care facilities, it is essential that they receive during the course of their lives a good basic education for health.

Certain far-sighted physicians have been pushing for this since the early 1930s. At first there was but little effective liaison between the Department of Health and the Department of Education. In recent years this has been improved, but still there is but little education for health within the school system. In the last decade the Connecticut State Medical Society also has been pushing for this, but the advocates don't push hard enough, and they are too few.

This is one of those things that everybody seems to be for but for which nobody can raise an effective campaign. Bills to this end introduced into the legislature over the last few years by the CSMS, the Council on School Health and the Department of Education itself have never had much of any vocal opposition but always seem to die in committee. I suppose the reason for this is that it would cost a certain amount of money. Another reason is that if one introduced courses on Education for Health Kindergarten through Senior Year High School, certain incumbent courses would have to be displaced. General inertia resists those who would rock the boat or interfere with the status quo.

Another trouble is that although the CSMS has backed this program for years, not enough individual physicians are interested at the local level to sell the idea to the local school boards (Hamden is a notable exception).

This is hard to believe when one stops to realize how basic good education for health is in our society today. Some people resist all education for health because sex education is even a small part of it. Drug education programs and anti-smoking programs are more acceptable; but when one mentions venereal disease or sex education, our puritanical ancestors turn over in their graves and scream their heads off.

Crisis oriented programs such as advice for non-wed mothers, drug abuse programs, etc. are fine but they are not sufficient. Some organizations have health education programs for the elderly. Physicians do a great deal of education for health in their offices. Some hospitals have health education programs. These are great, and they should be expanded, but they are not sufficient.

What we need is a full curriculum of Education for Health for the captive audiences in our schools (Kindergarten through Senior High). This would lay a foundation for adult thinking in matters of health. Let's do something about it!

James H. Root, Jr., M.D.
President

Reflections From The Dean's Office

Robert U. Massey, M.D.

The controversy over whether motorists should be required to wear seat belts continues on both sides of the Atlantic, and, like many issues in which either the protagonist or antagonist feels some great principle is about to be violated, has given rise to eloquent oratory and profound pronouncements quite unconnected with the issue itself. Terribly important questions of constitutional law may have to be resolved before drivers and their passengers can be required to buckle up.

Meanwhile, drivers on the freeways are back to their usual 70 miles per hour trying to keep up with the trucks. Even the presence of a State Police vehicle has only slight effect in spite of 55 miles per hour posted limits. No one questions the right of the State to set and enforce speed laws. For complex reasons, known best to itself, the State prefers not to do so, however.

Renal transplantation programs last year had increasing difficulty in maintaining the supply of cadaver kidneys. One of the reasons was the decline in spectacular auto accidents. Young victims newly killed are an excellent source of transplantable organs. Perhaps the State in its wisdom let languish vigorous enforcement of the laws when it realized that to persist would endanger this critical source of viable kidneys. Neurosurgeons have reported a considerable decline in brain smashing head injuries. One would have to have a very subtle conspiratorial view of governmental decision-making to believe that a diminishing neurosurgical service influenced the decision to ignore the new speed limits.

Deaths from auto accidents fell about 25 percent in this country during the period after the oil embargo. In Connecticut the death rate on the highways fell from an average of 48 per month in the year preceding the 50 miles an hour limit to 27 per month in the following 6 months—a decline of 43 percent. Since last May the rate has risen again to 38 per month, only 10 percent lower than during a similar period last year![1]

About 60,000 Americans are killed in auto accidents each year and this number has been increasing faster than the population. Evidence from our recent unplanned experiment with a 55 miles per hour speed law suggests that from 15,000 to 25,000 lives could be saved annually by enforcing the law.

A new therapeutic agent or a new vaccine that could yearly prevent 15,000 deaths would be acclaimed as another triumph for modern medicine. Suicides account for about 20,000 deaths; society might be induced to go to great lengths to try to prevent half the suicides and fail.

The automobile is only one of the many environmental hazards that are controllable with our present knowledge and by invoking our present laws. We may hold that in the end knowledge makes no difference and that other forces are at work in shaping our laws. If our view of history is consistently and thoroughly conspiratorial, then, believing in the limitless power of our enemies, we can predict gloomier futures and final disaster with Calvinistic certainty.

While there are conspirators, just as there are spies, I doubt that we need believe all the stories. There has been significant progress toward rebuilding our shattered environment. Steps taken have often been too short and too few, but the pressures of inflation, energy shortage, and famine may force our masters now to act decisively. Physicians and others in the health professions can influence legislative directions. Government need not be the province of one profession only, nor the willing servant of one industry.

Accidental death, like death from old age, is not totally preventable in this physical universe. Unlike the peaceful dissolution of the healthy nonogenarian, accidental death is rarely a good unless irreparable maiming is the alternative. One argument to support uncontrolled speed is that death is preferable to life-long disability. One could calculate the economic costs of death and injuries; certainly in some instances sudden death may be better for both the victim and society. My hunch, however, is that with enforced 50 miles per hour speed limits both injuries and deaths would be reduced. Unfortunately, the potential saving of life will not impress our lawmakers sufficiently to mandate enforcement of a universal 50 miles an hour limit; the certainty that oil will be saved will finally compel the law. There is virtue in scarcity.

ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut, School of Medicine, Farmington, Conn.

REFERENCES

1. Figures supplied by the Connecticut Department of Transportation.

Connecticut Medicine

Editorials

The Challenge of Breast Cancer

Few doctors in Connecticut have not been affected professionally or personally within their own families by breast cancer. One of 15 women will ultimately develop the disease. This most common cancer of women strikes about 1400 patients annually in our state and about 40 per cent of them ultimately succumb. It is sobering to see statements that the mortality rate has not changed significantly over the last 30 to 40 years. Balancing this, however, is progress on many fronts which gives reason to anticipate real improvement in this discouraging area. Recent studies by Spiegelman and his colleagues in New York have implicated a probable viral agent which may aid in the identification much earlier. Exciting new diagnostic techniques, such as xerography, thermography, and increased intelligent utilization of mammography should improve case finding. Better insights as to the appropriate type of primary treatment, as discussed by Dr. Ira S. Goldenberg in this issue of *Connecticut Medicine* are emerging. The spreading use of megovoltage radiotherapeutic equipment materially improves the outlook for local control and worthwhile palliation of painful areas. The identification of estrogen binding sites on tumor tissue should add an entire new dimension to use of hormonal manipulation as therapy, treatments currently based on empirical rather than scientific judgment. Great improvements in the surgical approach to the pituitary coupled with better patient selection, as outlined by Dr. Van Gilder in these pages, have made hypophysectomy a practical, very worthwhile means of treating advanced disease, especially that involving the skeleton. Many non-hormonal cytotoxic agents have demonstrable activity in advanced disseminated breast cancer. Dr. Malcom S. Mitchell's article outlines the challenges of finding the proper sequence for their use, the best combinations, and the optimal time for their utilization. Recent data support the concept that chemotherapy should be given early after mastectomy in high-risk patients—i.e., those with several axillary nodes involved by tumor. It is safe to assume that this will soon be standard treatment rather than waiting for recurrences to develop.

Few diseases are as variable or cut across so many of the specialized areas of medicine as breast cancer. The tremendous surge in knowledge about it places increased responsibility on all physicians to ensure that their patients are able to benefit from it. There is no substitute, however, for careful examination of the breasts by the doctor at frequent intervals and instruction of the patient in breast self-examination. Early cases are found this way, and they are the ones being cured!

John C. Marsh, M.D.
Section of Medical Oncology
Department of Medicine
Yale University School of Medicine

Time Saver — Life Saver

Is it a FIRST? We think so. "FOLLOW-UP OF CANCER—a Handbook for Physicians" is the title of a manual sponsored and produced by the Connecticut State Medical Society, the American Cancer Society-Connecticut Division, and the Connecticut State Department of Health.

"Patients who have had malignant disease should have periodic follow-up examinations for life"—such was a resolution of the Cancer Coordinating Committee of the Connecticut State Medical Society, which years ago aimed to have "Every Doctor's Office a Cancer Detection Center." Now stimulated by this Committee, the Council of CSMS on April 5, 1973, "endorse(d) the principle that it is both proper and advisable for the attending physician to call patients back for appropriate follow-up examinations, and that this is not an unethical practice but, in fact, quite the contrary;" it is for the patient's benefit. The membership of the Society and the hospitals were to be so informed. Also the Cancer Society was requested to enlighten the public regarding the value of this principle as it relates to malignant disease.

But how should this principle be converted into action? At what intervals should a patient be seen? What type of physical or ancillary examinations should be done and at which visits? No two cancer cases—or persons—are identical, so no fixed standard can apply. It is often difficult for the family physician, and even for the specialist, to remember every detail of what might be done and to decide which is important and which is an unnecessary expense and burden to the patient. It seemed inefficient to undertake the mammoth task of bringing up to date the 1946 "CANCER—a Handbook for Physicians" (a joint publication of CSMS and the State Health Department), or to duplicate the current yet-unpublished effort of the American College of Surgeons. Rather something novel, a pamphlet confined to follow-up and in as concise form as possible using tables and charts and a minimum of verbiage could be "of practical, not just philosophical theoretic assistance." An appropriate page could be photocopied and placed in a patient's chart. It would be a TIME-SAVER for physicians and hopefully a LIFE-SAVER for some patients. We are not aware of any similar previous publication.

The Committee ovum thus fertilized divided into seven cells, each destined for one special body system. Much data drawn from various sources, especially the world famous Connecticut Tumor Registry (another product of this triumvirate), was combined with the knowledge and experience of over sixty physicians as the fetus matured which is currently being delivered. No attempt has been made to deal with all cancers. A brief preamble provides some general principles of follow-up and ways to use the manual. Some sections discuss the habits or nature of that cancer, where to look for recurrences and the risk of new primary tumors. Today if found early, recurrences can often be cured.

"Follow-up of the malignant disease is of course vital and largely scientific, but follow-up of the patient" is equally important. Emotional support during those uncertain years or when little can be done medically can indeed be helpful. Also this periodic contact, questioning and examination militates toward early detection of new tumors and increases the improved cure-rate. Patients are more likely to receive a good physical survey: with rectal examination and sigmoidoscopy, with Pap smear and pelvic examination, with mammography in high risk women, and so on.

A sample follow-up card, available to any physician in quantity from the Connecticut State Medical Society, accompanies the Handbook. These can be used, along with a tickler file, to call patients back on time. This eye-catching 9″ x 6″ Handbook in its rich red cover with bold white and black letters is being distributed gratis, one copy to each physician with a license registered in Connecticut. It should be emphasized that these are guidelines, not standards of practice. The Committee hopes they will be useful and help elevate the quality of care.

A CANCER PATIENT LOST TO FOLLOW-UP CAN BE A CANCER PATIENT LOST!!

E. Tremain Bradley, M.D.

THE AMA AND DUES

By the time this reaches our members, most will have read about the AMA meeting in Portland. Let me, however, add a bit about the issues related to dues, the subject that overshadowed all others. First, let there be no misunderstanding—it is the House of Delegates that is the policy-making body of the AMA, not the Board of Trustees or Staff. Most men here who talked to me after the initial press release of the Board recommending the dues increase and discontinuance of advertising in AMA journals took it as a fait accompli. *Neither was* adopted by the House. Strong objections from the delegates as they arrived caused the Board to change its stand on ads even before the House convened. Also, the House voted a one-shot assessment of $60.00, leaving the question of an annual dues increase until the June meeting so as to give time for a committee of the House to study, with the Board of Trustees, not only dues but priorities of the AMA.

Generally AMA meetings are the most stimulating and interesting of any organization I attend. It is a time to hear what colleagues as well as students, interns and residents from different parts of the country think. The influence of regionalism on the thinking of delegates has been the single most educational and interesting fact to me, analogous to what we read about the U.S. Senate. This meeting, however, was the least enjoyable of any such meeting I've attended. The implications of dues permeated the whole meeting. It was not the amount of the suggested increase, but its abruptness and the wholesale elimination of important committees, programs, and publications before the delegates had the opportunity to study them that created an atmosphere of disquiet. It was a New England resolution, germinated by our Trem Bradley, that finally carried the day; it called for a continuation of all journals and of the structure and names of all committees until after a complete report of the study has been made in June.

In these times if the fiscal report we received had been the work of a large business corporation, it would have given rise to questions of mismanagement or malfeasance. The latter possibilities were immediately and completely eliminated. Without hunting for scapegoats, the delegates did, however, feel that the urgency of the recommendations reflected something less than outstanding management, though other institutions, foundations, universities, and governments certainly are going through the same problems due to inflation, increasing costs, and catastrophic depreciation of portfolios.

There was no doubt that the AMA was in acute financial trouble from a sudden decrease in *liquid assets,* so much so that it has had to borrow heavily to pay for *current operating expenses.* But instead of a recommended annual dues increase of $90 based on projections for five years, the House voted the assessment to take care of instant problems, gaining time for more study until the next meeting. This should also provide an education not only for the delegates, but for the entire profession and, if the media will give it any attention, the public. Most programs marked by the Board for elimination directly or indirectly benefit the public.

Take the Council on Medical Education, one of our most important, prestigious, and costly committees. It is committed to all divisions of medical education, undergraduate, graduate, and continuing medical education, to the allied health professions, to the new programs on physicians' assistants, to the American Specialty Boards, Physician Manpower problems, and others—each requiring an active subcommittee, made up of outstanding physicians in the country, and of course with paid staff. Instead of being cut, this Council should be expanded.

The malpractice problem necessitates another committee, staff, and financial support. PSRO, another. And as federal legislation increases, this means more study for the AMA, and money. Every bill introduced in Congress (I believe there were about 2,000 during the last session) must be studied and reported on, with a critique.

It is unfortunate though understandable that most physicians do not know about the general programs, let alone the details of them. Let me illustrate with one issue of a few years ago not generally recognized or appreciated then or now, even by those involved (the hospital-based physicians) during the Medicare and John Knowles era. These were the radiologists, anesthesiologists, pathologists, and physiatrists. When Dr. Knowles was suggested for appointment as HEW Undersecretary of Health, he made it clear that such specialists should be salaried employees of hospitals and not treated like other physicians in practice. There is little doubt that it was the clout of the AMA that prevented his viewpoint, shared by many in Congress, from prevailing. My experience has been that few of these specialists realized the AMA's role then, and now even deprecate the AMA. Though their own specialty associations spoke up, their influence was suspect as self-serving and minor compared to the AMA's. Even the few who understand this seem now to say, but what have you done for me lately?

During the next few months, AMA and state society news facilities will inform the profession of AMA problems and what it is doing about them. It is hoped that members will read these reports and ask probing questions. Most of us live in a small cloistered world, and so long as our own practices are safe and as free as possible, we are satisfied. But this requires other physicians to work in their associations to preserve their freedom.

Connecticut Medicine will publish everything reasonable and legitimate to inform the membership about the AMA. I wish every physician could attend one of its meetings, not only for the excellent clinical sessions but to observe reference committee hearings and proceedings of the House which are open to all physicians, the press and public. Any physician may express his opinions on resolutions in reference committee hearings; they are analogous to Congressional hearings. I am sure his impression of the AMA would give him pride.

I have heard many criticisms about poor public relations both within the AMA and the state societies. If any one of our members has any suggestions as to how to inform our membership about the AMA or our State Society, I invite him to send them to our leadership and the Editor of *Connecticut Medicine.* Let us withhold judgment about dues and programs until we find out more about them. I think it is reasonable and fair to expect that a mature, educated physician will do just that.

Fred Fabro, M.D.

Medicine in the Boondocks

Who are the Good Guys?

Some time back I suggested to the Editorial Staff of this Journal that short pieces written from the the perspective of rural medicine would offer our readers a valid and somewhat neglected viewpoint. The reception was cordial, but subject matter was not easy to choose. Moreover, it proved difficult to generate a good honest discussion of our problems and air them to our more sophisticated brothers.

No one likes to air soiled linen, especially if he has old fashioned undergarments and the rural practitioners, bless their tradition-burdened hearts, are understandably defensive.

Defensive? Embattled is more like it. They are working furiously to keep up with a population too large to handle comfortably and looking anxiously over their shoulders at a host of regulatory groups, government, insurance carriers, public commissions and consumer organizations.

The medical literature is glutted with new techniques and complex changes in concepts of disease, so that when the rural practitioner can grasp a moment to sample his journals, his anxieties are merely intensified at the prospect of ever broader fields to conquer.

It is probably unkind, then, to suggest that the overload of work can sometimes serve as an excuse to save him from too much self-criticism. He has such a generous supply of villains on which to blame his shortcomings, that he may easily slip into self indulgence regarding his efforts to keep up.

To complicate matters, there are methods by which the appearances of stringent self discipline can be maintained without much underlying substance—taking courses without evaluating the results; going through the paces of regulatory committee work without ever coning in on abuses (after all, the man eats lunch with you almost every day); never really admitting the strength of economic motives in structuring office practices vis-a-vis the hospital medical demands.

All these factors are human enough and while we can take comfort that we do more self searching than any other profession, we must not beguile ourselves into thinking we are doing enough. We are, after all, under a greater burden of responsibility than other professions.

As these ideas crowded in on me, I thought of the ease with which we can blame our woes on the *Bad Guys*. It further occurred to me that it would be a useful exercise to list these *Bad Guys*, the better to envision the scope of our problems.

If a large and overbearing Federal Government has even a small virtue, it is that it can unquestionably assume the role—with every justification—of number one *Bad Guy*. In this brief essay, no more need be said about this cumbersome and wasteful level of organization.

The State is a more mixed bag but can be both extraordinarily helpful and a damned nuisance. Again the mention of State and Federal Agencies is enough—they are easy marks for assigning villainous roles.

Then we get to our regional and national organizations, in particular, the Joint Committee on Accreditation of AHA and AMA. In their exceptionally valuable work, the men performing the dulling task of checking on the hospitals sometimes indulge in nit-picking, or seem to be doing so to the subjects of their scrutiny. They are easy to classify as *Bad Guys*, too, and to excuse deficiencies they detect by dismissing the items as of no real importance or not fully understood by the examiners in the context of "our own unique sense of responsibility."

And so on down the line. In the view of the harried practitioner the professors who write about peer review become ivory tower figures; the specialty journals seem to remain too distant from the firing line to offer understanding; the local experts aren't really accepted as qualified ("A prophet is not without honor, save in his own land").

P.A.S. statistics, if they suggest we are not keeping pace, are often felt to reflect "unreal goals" from distant centers or to be derived from too broad a base. Peer Review Organizations are under ferocious attack, particularly from the rank and file (if someone can supply an unhackneyed phrase for the ordinary membership in our profession, I would accept it with relief). These attacks are at least in some measure deserved since misapprehensions are widespread and effective efforts to arrive at mutual goals have stumbled over maladroit presentations and mutual mistrust from both medical and lay positions.

One could go on and on, but it is time to seek some honest answers, some realistic goals and some effective self-examination.

We are certainly not going to claim, particularly in the rural setting, to generate enough of our own expertise for comprehensive self-examination. And while it is possible for us to perform effectively as self-policing bodies, experience suggests this is a rare accomplishment. I am even suspicious that accounts in national publications of successful peer review are a more artful form of self-delusion than we have been able to devise.

Very well, then, it would seem that any agency or individual attempting a policing function, at whatever level, is assigned to *The Bad Guys*.

If this is so, who are *The Good Guys?* Who can tell us we are not doing well enough and in doing so command our respect? There may be, for each of us, a few *Good Guys*—professors from our own training grounds or authors from our own specialty journals—but one man's mentor is another man's pedant.

I have no answers and would welcome a few. My best guess is that there are a great many *Good Guys* around and are not as many *Bad Guys* as we imagine. At all events, we had better find some acceptable *Good Guys* soon or we will forfeit the game.

JOHN L. MEYER, II, M.D.

Letters To The Editor

Letters to the Editor are welcomed and will be published, if found suitable, as space permits. Like other material submitted for publication, they must be typewritten *double spaced* (including references), must not exceed 1½ pages in length and will be subject to editing and possible abridgment.

COMPREHENSIVE PSYCHIATRIC PLANNING

To the Editor: In the June, 1974 issue of *Connecticut Medicine* appeared an article, "A Comprehensive Plan for Psychiatric Services for the Capital Region," by Healey, et al, which contains substantial inaccuracies, at least with respect to the Institute of Living. I would like to make the following observations:

1. The Institute of Living is described as having "approximately 200 beds." In fact, the Institute of Living has 415 inpatient beds, plus a Day Treatment Center and Outpatient Clinics for adults and children. These are simple, straightforward facts, which have not changed for at least 20 years and which would have been available to the most casual inquirer.
2. The article states, "in effect the great majority of treatment available is for the wealthy (Institute of Living)." This conclusion is based presumably on the same quality of research as the previous statement about the total number of beds. The Institute of Living makes no more assessment of patients' financial status than any general hospital, and we have no way to determine the percentage of patients who are "wealthy." We do know that, as in every other health care facility, over 80% of patients are residents of the Institute of Living because they have health insurance coverage provided by their employers or by their own policies, or by governmental programs, such as Medicare.

   There is one notable difference between the patient population at the Institute and that in any general hospital. We have no sizable number of medically indigent inpatients because, unlike the general hospitals, there is no standard arrangement by the State Welfare Department to finance such services. The Institute of Living has had, for some 20 years, an arrangement with the State Welfare Department to admit up to eight patients under the age of 18, at any given time. The limit, as to number, is imposed by the State Welfare Department and not by the Institute of of Living. For this, the Institute is paid $50.30 per day to cover all expenses, including the full range of psychiatric treatment services. The authors must surely be aware that the current rates paid by the State Welfare Department to general hospitals in the Hartford area range from a minimum of $151.08 to a maximum of $173.32 per day.
3. Adult and Children's Outpatient Psychiatric Services, operated by the Institute of Living, serve only medically indigent patients in the Hartford area. Fees are graduated in accordance with the financial means of the patient or his family. Last year, patients' fees totaled $23,002. The cost of the operation of the Clinics was $337,336. The Institute of Living is grateful for the contributions from business, industry, and the citizens of the Greater Hartford area which assist in making these services possible.
4. The present fee at the Institute of Living for private patients in shared accommodations, *including psychiatric treatment,* is $71.00 per day. We invite the authors to contrast that fee with those available in any other proprietary or non-profit psychiatric facilities, either in Connecticut or elsewhere.
5. Finally, the authors observe that "little is locally available for those seen as severely disturbed, (i.e., those thought to be suicidal or showing bizarre behavior)." During fiscal 1973, the Institute of Living admitted 107 patients from the Greater Hartford area. Sixty-one were considered moderately to severely disturbed or suicidal. Inquiry by the authors would have readily revealed that patients are regularly transferred from the Greater Hartford general hospitals to the Institute of Living precisely for this reason.

Comprehensive Health Planning is by no means an exact science. Unless, however, it has solid grounding in carefully researched facts, it becomes merely an exercise in fantasy.

John Donnelly, M.D.
Psychiatrist-in-Chief
The Institute of Living

Hartford, Conn.

The above letter was referred to the authors of the article in question who offer the following reply:

To the Editor: We apologize to John Donnelly and the Institute of Living for the errors that appeared in the article and misinterpretations that accrue from this. The authors of the article on the "Comprehensive Mental Plan for Psychiatric Services for the Capital Region" have no argument or disagreement with the Institute of Living or any other institution in the Region which may have been left out and misrepresented in the plan.

The article about the plan is very brief and necessarily had to be short on details. We still feel that the plan is a vital one and in the spirit of which it was put forward, that is, a vehicle for community planning, it still has credibility. The main obstacles to development of regional coordinated mental health delivery systems rest in the narrow interests of institutions, and their inability to serve the needs of individual clients and the community, and their tendency toward self-preservation and aggrandizement.

It may well be that under the new enlightened Democratic administration we'll see real movement towards the coordination and improvement of mental health services for the ordinary citizens of Connecticut.

James C. Healey, M.D.

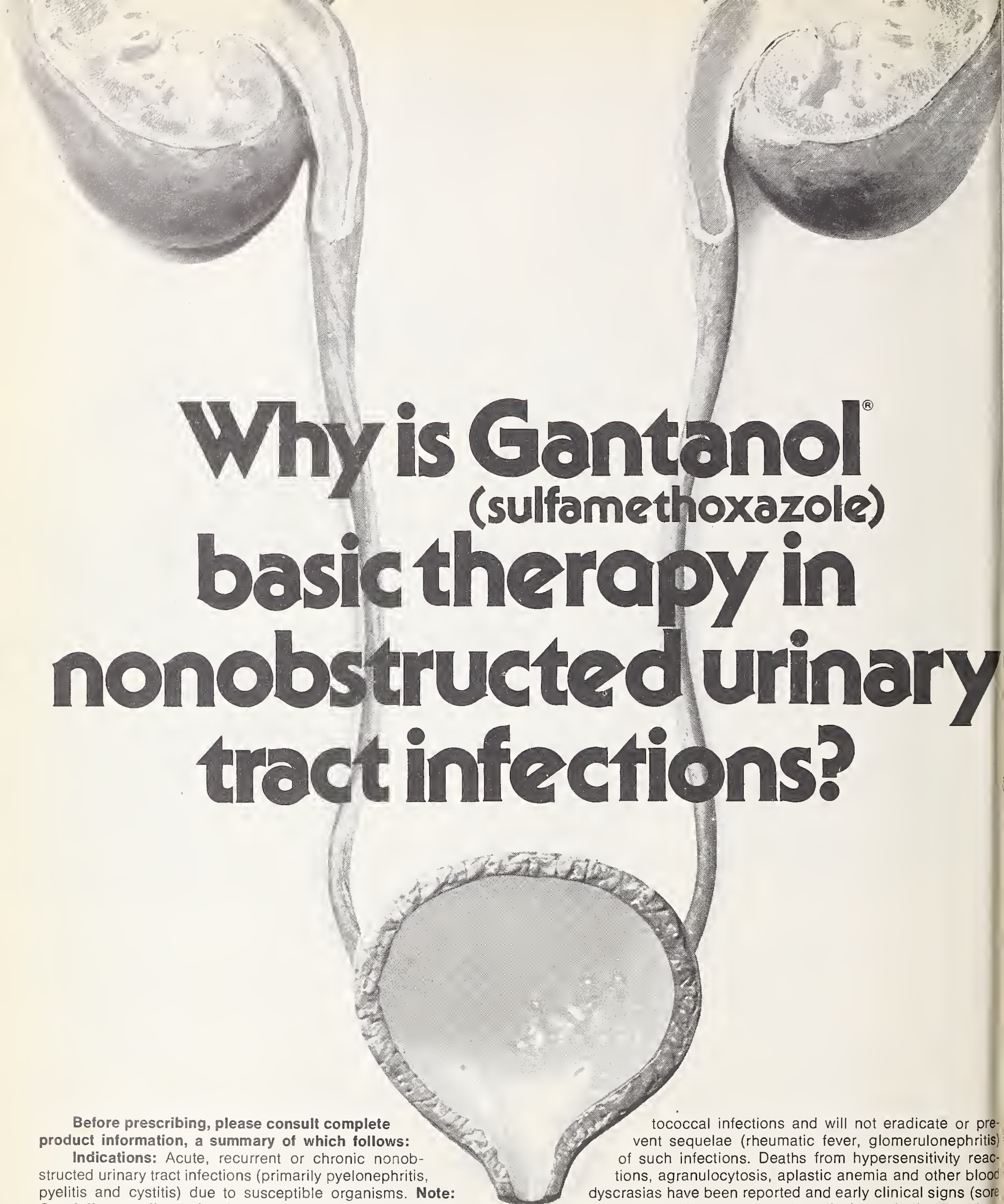
University of Conn. Health Center
Hartford, Conn.

CLEAR YOUR MEETING DATES THROUGH CSMS

Society members are urged to take advantage of the CSMS service which maintains a calendar of all major medical meetings in the state.

Far too often, there is a conflict in the dates of these meetings, which involve many of the same medical leaders. It is unfortunate, for instance, when a major county hospital holds a meeting at the same time as an annual meeting of the county Association or the House of Delegates of the State Medical Society.

To avoid these conflicts physicians are asked to call the CSMS office, listing the dates of their meetings and to check to see if any other events have already been scheduled for the same time.



Before prescribing, please consult complete product information, a summary of which follows:

Indications: Acute, recurrent or chronic nonobstructed urinary tract infections (primarily pyelonephritis, pyelitis and cystitis) due to susceptible organisms. **Note: Carefully coordinate *in vitro* sulfonamide sensitivity tests with bacteriologic and clinical response; add aminobenzoic acid to follow-up culture media. The increasing frequency of resistant organisms limits the usefulness of antibacterials including sulfonamides, especially in chronic or recurrent urinary tract infections.** Measure sulfonamide blood levels as variations may occur; 20 mg/100 ml should be maximum total level.

Contraindications: Sulfonamide hypersensitivity; pregnancy at term and during nursing period; infants less than two months of age.

Warnings: Safety during pregnancy has not been established. Sulfonamides should not be used for group A beta-hemolytic streptococcal infections and will not eradicate or prevent sequelae (rheumatic fever, glomerulonephritis) of such infections. Deaths from hypersensitivity reactions, agranulocytosis, aplastic anemia and other blood dyscrasias have been reported and early clinical signs (sore throat, fever, pallor, purpura or jaundice) may indicate serious blood disorders. Frequent CBC and urinalysis with microscopic examination are recommended during sulfonamide therapy. Insufficient data on children under six with chronic renal disease.

Precautions: Use cautiously in patients with impaired renal or hepatic function, severe allergy, bronchial asthma; in glucose-6-phosphate dehydrogenase-deficient individuals in whom dose-related hemolysis may occur. Maintain adequate fluid intake to prevent crystalluria and stone formation.

Adverse Reactions: *Blood dyscrasias* (agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, hemolytic anemia, pur-

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pura, hypoprothrombinemia and methemoglobinemia); *allergic reactions* (erythema multiforme, skin eruptions, epidermal necrolysis, urticaria, serum sickness, pruritus, exfoliative dermatitis, anaphylactoid reactions, periorbital edema, conjunctival and scleral injection, photosensitization, arthralgia and allergic myocarditis); *gastrointestinal reactions* (nausea, emesis, abdominal pains, hepatitis, diarrhea, anorexia, pancreatitis and stomatitis); *CNS reactions* (headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo and insomnia); *miscellaneous reactions* (drug fever, chills, toxic nephrosis with oliguria and anuria, periarteritis nodosa and L.E. phenomenon). Due to certain chemical similarities with some goitrogens, diuretics (acetazolamide, thiazides) and oral hypoglycemic agents, sulfonamides have caused rare instances of goiter production, diuresis and hypoglycemia as well as thyroid malignancies in rats following long-term administration. Cross-sensitivity with these agents may exist.

Dosage: Systemic sulfonamides are contraindicated in infants under 2 months of age (except adjunctively with pyrimethamine in congenital toxoplasmosis).

Usual adult dosage: 2 Gm (4 tabs or teasp.) initially, then 1 Gm *b.i.d.* or *t.i.d.* depending on severity of infection.

Usual child's dosage: 0.5 Gm (1 tab or teasp.)/20 lbs of body weight initially, then 0.25 Gm/20 lbs *b.i.d.* Maximum dose should not exceed 75 mg/kg/24 hrs.

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Hospital Governing Board and Medical Staff Relationships

Betty Jane Anderson, J.D.

During the past few years, the number of disputes between hospital governing boards and organized medical staffs has been increasing at an alarming rate. The basic issue in these disputes is relatively simple: are hospitals or physicians primarily responsible for the care and treatment of patients? Will the patient of tomorrow look to a particular physician to guide his treatment from sickness back to health or will he look to a hospital?

The hue, cry and concern about the corporate practice of medicine is not a new battle cry. Resolutions of the AMA House of Delegates have deplored the corporate practice of medicine in the United States practically since the founding of the AMA. The present ramifications of corporate practice of medicine, however, are different and more sophisticated than ever before.

In the past, laymen seeking personal financial gain endeavored to hire physicians, exploit them and sell their services at a profit. Some proprietary hospitals operated for profit similarly hired physicians on a salary basis, sold their services and profited while perhaps providing poor services because only incompetent or inept physicians were tempted by the salary offers. Today, the threat of corporate practice involves many of the finest hospitals and teaching institutions in the United States; well-funded community hospitals and teaching hospitals allied to prestigious universities and medical schools. Consequently, the threat of the corporate practice of medicine to the interests of the patient and the physician is more real and more insidious than ever before.

When a university affiliated teaching hospital becomes more interested in treating individuals as teaching material than in treating them as patients, when research is given higher priority than success in treating individual patients, when staff physicians are subjected to constant pressure to publish journal articles and obtain research grants, individualized patient care yields and the corporate spector—the image of the corporate giant versus the individual physician—becomes a matter of deep concern for practicing physicians. Teaching and research have their proper place, but the physician-patient relationship should be dominant. The corporate practice of medicine, or perhaps more correctly, the trend of hospitals to engage in the corporate treatment of patients is now spreading to non-teaching hospitals and is reported with increasing frequency in hospitals operated by religious organizations.

If the medical care of patients is to remain the primary responsibility of physicians and not impersonal corporations, then it is mandatory that the organized medical staff of a hospital truly functions as the name implies with emphasis on the word "organized." The hospital medical staff is and should be more than a group of individual physicians who have some sort of relationship to the hospital and its governing board by virtue of the hospital privileges accorded them individually.

The individual medical staff physician has an obligation to the organized medical staff; the obligation to participate productively and responsibly. Likewise, the organized medical staff has a basic obligation to discipline its members so that together they may fulfill through self-government and self-direction the medical management of the hospital. If the medical staff defaults in this obligation, the governing board can be expected to react. When laymen alone attempt to make decisions which should only be made upon the recommendation of physicians, patient care can be expected to suffer and the concept of professionalism to deteriorate.

To provide for the best interests of patients and the physicians who serve patients, the governance of the hospital should function as a partnership between the governing board carrying out its responsibility for the business management, operation and administration on the one hand and the organized medical staff carrying out its responsibility for the medical management of the hospital on the other hand.

The governing board of the hospital is entitled to an organized medical staff that governs the medical affairs of the hospital efficiently, economically, and in the best interests of the patients, the physicians and the institution. The medical staff should be well organized and exercise its self-governing prerogatives diligently and responsibly.

BETTY JANE ANDERSON, J.D., has been appointed Director of the Department of Health Law, a new department in the office of the General Counsel. The Department of Health Law will be concerned primarily with legal matters related to health care legislation and physician-hospital relations.

Delivered before the North Central Medical Conference Program, Radisson South Motel, Bloomington, Minnesota, October 20, 1973.

The governing board of a hospital is a lay board. It is a lay board even though some of its members may be physicians. Whether the governing board of the hospital is composed entirely of laymen or includes some or all physicians, neither the hospital nor the governing board as such is licensed to practice medicine. Only physicians are authorized legally to practice medicine.

This brings us to the question of whether it is desirable, important or necessary for the governing board of a hospital to have physicians as members. There have been instances where governing boards have engaged in the practice of making medical decisions reflecting the views of physician board members.

A physician on the hospital governing board is there to act in a management capacity and not to make medical decisions. Some medical organizations, including the AMA, have advocated having at least one physician on the hospital governing board. This can work well if the purpose is to have a conduit for communication between the governing board and the medical staff. It can work well if the physicians so included are not engaged in making decisions that should emanate from the organized staff itself.

The physician member of a hospital governing board who does not serve as a conduit of communication and who does not sit as a representative of the medical staff often is responsible for engendering disputes between the governing board and the medical staff. This can occur if the governing board relies more on the physician member for medical input than on the organized medical staff. What is important is not whether a physician is on the governing board but whether two-way communication between the governing board and the medical staff is currently and intelligently maintained.

Ideally, a hospital's primary objective—that of providing high quality patient care services for the community—can be achieved best if there is a close working relationship and effective cooperation between the two groups who share the responsibility for hospital operation: (1) the board of directors or trustees responsible for the business management, housekeeping and prudent use of the institution's resources to attain quality patient care; and (2) an organized staff of physicians practicing within the hospital and responsible for the methodology and implementation of the system under which the resources of the medical community are used to provide the best attainable quality of medical care and services.

In some hospitals, the governing board apparently suffers from the misconception that it is responsible for making medical decisions and exercising medical discretion in assuring high quality patient care.

The governing board is a lay instrumentality of hospital management. The board is responsible to the community, to charitable donors, to governmental agencies that provide funds, but first and foremost to patients. The board is responsible for seeing to it that funds are spent wisely to bring together the best available facilities and services that budgetary considerations can provide for quality patient care.

The governing board's responsibility includes permitting only qualified competent practitioners to use the hospital facilities. With respect to physicians, a lay board frequently can make negative judgments as to ethical, moral and medical competence to practice. For example, laymen are capable of determining that physicians with criminal records or those excluded from other hospitals because of medical malpractice or lack of reasonable cooperation with the nursing staff and the hospital administrator should not be permitted to practice in the hospital. With respect to medical evaluations, the fact-finding of medical competence or incompetence must be left to the physician's peers who have observed his performance and evaluated his ethical and professional credentials.

It has often been said that the governing board of the hospital is legally and morally responsible for the quality of patient care within the institution. Unfortunately, these words have been misinterpreted—sometimes innocently and sometimes deliberately—with respect to physicians' services. In the case of salaried physicians, responsibility may mean that the hospital is liable in damages for their malpractice. Even with salaried physicians, however, the courts are divided as to whether the hospital is or is not liable for their professional services.

In some of the states where hospitals have been held legally responsible for the negligence of salaried physicians, the courts have treated physicians serving as independent contractors when providing medical services in the hospital as if they were employees in cases where the hospital furnishes the services of the physician and the patient has no voice in his selection. Included in the category of physicians who are independent contractors for purposes of providing professional services in the hospital but employees for purposes of patient liability are anesthesiologists, pathologists, radiologists and physicians serving in the emergency department.

There is not one single reported case in which a hospital has been held legally responsible for the malpractice of an attending, competent physician engaged in independent practice and selected by the patient.

Some hospital consultants, hospital administrators and their attorneys have spread an erroneous interpretation of the *Darling* case with such frequency that there seems to be a generally held opinion that the misinterpretation accurately reflects the law of the land. Nothing could be further from the truth. In the nine years since the *Darling* case was first tried, it has either been entirely rejected by other courts or narrowly construed.

Darling is an Illinois case and even in Illinois the case has been given a narrow construction. Some of those hospital administrators, governing boards and their attorneys who cite *Darling* as a precedent would have physicians believe that the hospital is jointly responsible for any act of malpractice they may commit in the delivery of medical services within the hospital. With this as a base, they say that if the hospital is responsible for the attending physician's mistakes, it has the right to supervise and direct his services. This is not what the *Darling* case holds.

Before a hospital can be held liable for the mistakes or negligence of an independent, attending physician, there must be some showing of negligence on the part of the hospital. The hospital must be proven negligent in its own right. Hospital negligence can be found, for example, if a physician of known incompetence is permitted to continue practicing in the hospital or is granted privileges.

In the *Darling* case, the facts are basically simple. The services of the physician as described in the case clearly show negligence. Although the physician involved was not an employee of the hospital and was engaged in the independent practice of medicine, nevertheless, the services from which the negligence arose took place when he was on emergency call.

Darling, who received negligent care in the setting and follow-up treatment of a broken leg, did not select the physician. The physician was on emergency call and provided by the hospital. Insofar as the medical care delivered, a physician selected and provided by the hospital has status similar to one who is on a salary basis.

In essence, the court held the hospital responsible for the physician's negligent treatment; first, because his services were provided by the hospital, and secondly, because the facts of the case show and the court found that the nursing care was negligent. The nurses failed to call attention to what was obviously a gangrenous condition as evidenced by the continuing excruciating pain of the patient and the foul and putrid odor that filled the room.

The reported cases in the various states following *Darling* either have rejected the case as a precedent or have followed it as precedent for hospital liability for employee negligence.

The developing trend on the part of some hospital governing boards to attempt to exercise direction and supervision over staff physicians in reliance on the *Darling* case is widespread enough to be of grave concern. In some of these hospitals, such control is exercised by the governing board's appointing salaried department heads, salaried chiefs of staff and a medical staff executive committee of salaried physicians. The members of the attending staff then become subject to the direction of the salaried physicians. Under these circumstances, the medical staff is not self-governing and has no separate existence as a deliberative medical body.

When the chain of command and control stems from a lay governing board, there are influences which conflict with the physician's undivided loyalty to his patient. Salaried physicians in a line of command to the governing board have divided loyalties between the interests of the institution and those of the patient which ideally should not be in conflict.

In some institutions, the situation has become so grave as to create a line of authority that goes from the attending staff to a salaried medical hierarchy which in turn is responsible to a hospital administrator—often styled as President of the hospital and frequently not only the chief hospital executive but the dominant voice on the hospital governing board. In institutions where the hospital administrator occupies the role of hospital president and chairman of the hospital governing board, the only line of communication between the governing board and the medical staff is through him. This is lay domination at its zenith and a trend that should be aborted as early as possible.

It is too late in time and not practical to turn back the clock and engage in a campaign against the salaried employment of physicians in hospitals. Quality care requires that the employment of salaried physicians in hospitals should be subject to the condition that the salaried physicians must obtain and continue their hospital privileges in the same manner as other attending physicians; that is, upon the recommendations of the organized medical staff following evaluation of their credentials. In the absence of any clear showing that the organized medical staff has abused its functions, its recommendations should be accepted by the governing board.

Physicians function best when they are self-governing, when they accept the supervision and direction of their peers' evaluations and are selected through democratic processes. Attending physicians who are salaried and depend only upon a lay governing board for their authority do not normally receive the respect of other physicians. Their position is given to them by laymen and not earned through medical achievement and recognition.

Unfortunately, medical democracy can only be achieved where the governing board is enlightened and follows the procedures recommended by the Joint Commission on Accreditation of Hospitals. The courts are not available under existing laws and judicial precedents to guarantee a medical staff self-governance and self-determination in medical affairs. No court has held a not-for-profit hospital to be engaged in the illegal practice of medicine although in a few jurisdictions, such as Iowa, there are statutes that prohibit the corporate practice of medicine by hospitals.

How can physicians protect their professional rights and assure self-governance in medical matters in the hospital setting? It does not seem likely that any court would rule that salaried physicians within the hospital must be cleared by the medical staff and continue as members of the medical staff. How can individual attending physicians protect themselves from dominance by full-time salaried chiefs of staffs? How can medical staffs assure themselves a direct line of communication to the governing board? What weapons are available to a medical staff in dealing with a recalcitrant or misguided governing board?

Although physicians engaged in the independent practice of medicine are largely entrepreneurs with respect to their financial arrangements with patients, nevertheless such physicians have a great deal in common with salaried physicians when they treat patients in a hospital.

It is abundantly clear that the hospital privileges given to a particular physician should be quite explicit with respect to what he can and cannot do in the treatment of patients within the hospital. As a practical matter, the professional man performing services for a patient in a hospital is governed by rules that differ little from those of a salaried physician treating patients, for example, in a university affiliated hospital where all physicians might be on a salary basis.

The attending physician is given to understand what he can and cannot do in the treatment of patients. There are rules he must observe as to when he must obtain consultation. To a large extent he must follow a medical methodology and order tests as required by hospital rules. Like employees in an employer-employee relationship, his work is or should be under the constant surveillance and scrutiny of his peers in the framework of the organized medical staff.

In common with the employee, the so-called independent, attending physician is required to attend medical staff meetings; he is assigned committee chores; and he may be assigned involuntarily to take his turn on call in the emergency department. As is required by those who have an employee relationship with the hospital, the attending physician's hospital privileges require him to observe the administrative rules and procedures of the hospital which the governing board or the hospital administrator may establish for the orderly operation of the hospital.

The physician who loses his hospital privileges for cause has a great deal in common with the salaried physician who is fired for cause. It is a truism that the physician's hospital privileges make him just as economically dependent on the hospital as an employee is on his employer.

If it is true that attending and salaried physicians have numerous characteristics common to their occupational performances, it is likewise true, even though some physicians may prefer not to engage in such comparisons, that the hospital and its governing board have a relationship to the attending physician quite comparable in nature and responsibility to the governing board's relationship to employees in the hospital.

The governing board is obligated to be selective in granting hospital privileges to qualified physicians. In executing this function, it should rely on the evaluation of professional attainments made by the organized medical staff. Without belaboring the point, it is quite obvious that the hospital, either directly through the administrative processes of the governing board or through the operation of the organized medical staff functioning on behalf of the hospital, exercises a great deal of control over the attending physician; control that matches the control employers exercise over employees.

Furthermore, just as there is close economic mutual dependence between employers and employees, there is perhaps an even closer mutual dependence between the hospital and the attending physician who is responsible for bringing patients to the hospital.

Identifying the common characteristics of attending, independent physicians and employees has great legal significance. Employees have strong, legally protected, economic weapons which they are entitled to use in "labor disputes" with their employers over terms and conditions of their employment. The Clayton and Norris-LaGuardia Acts specifically exempt "labor disputes" from the application of the Sherman Antitrust Act.

The term "labor dispute" is not limited exclusively to those persons who are wage earners. In the case in which the AMA was held to be in violation of the Sherman Antitrust Act, the United States Court of Appeals by way of an aside pointed out that there were circumstances under which physicians who were entrepreneurs could qualify for the same protection afforded wage earners engaged in labor disputes. In other words, where the issue involves the terms and conditions under which labor is expended, whether by wage earners or independent contractors, the exclusion from the antitrust laws should be applicable.

In general, the federal antitrust laws prohibit unreasonable restraints against interstate commerce. Hospitals have been held to be engaged in interstate commerce and therefore subject to the antitrust laws and entitled to the protection of the exceptions to those laws.

In a dispute between a hospital governing board and the organized medical staff, what are the limitations upon what the medical staff can do to enforce its demands concerning the terms and conditions under which attending physicians serve patients in the hospital? What can the medical staff do to protect itself against a governing board that wants to make physicians the servants of the hospital rather than the patient? What can the medical staff do to protect medical professionalism from conversion to the institutionalized practice of the healing arts? What can be done to prevent the hospital-patient relationship from becoming dominant over the physician-patient relationship?

The antitrust laws prohibit unreasonable restraints. Reasonable restraints are not prohibited. At a minimum, the organized medical staff can use reasonable measures to improve the terms and conditions under which its members exercise hospital privileges and undertake counter measures to the actions of the governing board. Reasonable in such cases would be determined in light of the action taken by the governing board.

Although the issue has not been litigated, in particular situations it appears that the organized medical staff should be entitled to the kind of economic and other weapons that trade unions, which are exempt from the antitrust laws when engaged in labor disputes, use in dealing with employers.

At stake in all of this is the physician's professionalism—the right to give top priority to the individual physician-patient relationship. Institutional objectives such as the provision of patient care that meets high statistical standards, sometimes is achieved only at the expense of the individual patient.

There is an important role for the medical society in all of this. If the medical staff is to function as a collective unit on behalf of its members, it must have the assistance and guidance of those who are professionals in the process of arbitration, mediation and collective negotiation. No matter how highly trained as practitioners, physicians are novices and not professionals in the art of negotiation and mediation.

Hospitals have governing boards of businessmen, trained administrators and highly qualified attorneys, sometimes even professional labor lawyers, who guide the hospital's dealings with the medical staff. Often this professional team of administrators and lawyers is not visible, but their guidance is always present.

In physician-hospital disputes, the medical staff must have a comparable team of experts if medical practice is not to be institutionalized. This should be the role of organized medicine with the county medical society at the firing line providing direction and guidance to equalize the bargaining position of the medical staff.

Just as the union provides a business agent and legal experts to represent employees in difficult dealings with their employers, the same kind of help should emanate from county and state medical societies with AMA participation.

It is no longer sinful or despicable for medical societies to be called physician unions. The National Education Association, for example, an old-line professional association of teachers, learned this the hard way after the AFL-CIO got into the picture. Now the NEA openly and aggressively functions as a union. If organized medicine is unwilling or unable to accept the challenge, then most assuredly the physician union movement will flourish and fill the vacuum. Unfortunately, they cannot do the job as well as organized medicine.

Physician-hospital disputes are not necessarily one-sided affairs. There may be instances where there are legitimate grievances on one side or the other or mutual grievances of a legitimate nature. A few instances have come to the attention of the AMA where the organized medical staff has been lax in instituting recommended reforms or in keeping bylaws current. The result has been that harsh consultants were called in by the hospital swinging the pendulum too far in the opposite direction.

A medical society that has objective, qualified professionals to help it can render the best service by objectively pointing out where and how remedial measures should be voluntarily undertaken. Responsible unions do this also when members fall out of line and the employer calls upon the union to help correct the situation.

Medical societies can help by preparing materials such as kits of educational materials. A do-it-yourself handbook is insufficient, however, to deal with a governing board that is represented by high-priced lawyers and professionally trained administrators.

Thirty-eight National Health Laws, 1968 - 1973

87th Congress

First Session

... The Practical Nurse Training Extension Act of 1961 (P.L. 87-22)
... To authorize training teachers of the deaf (P.L. 87-276)
... To increase the authorization of appropriations for the American Printing House for the Blind (P.L. 87-294)
... Community Health Services and Facilities Act of 1961 (P.L. 87-395)

Second Session

... To authorize grants for health services for domestic agricultural migratory workers and their families (P.L. 87-692)
... To amend the Act authorizing a loan service of captioned films for the deaf (P.L. 87-738)
... To authorize a National Institute of Child Health and Human Development (P.L. 87-838)
... Vaccination Assistance Act of 1962 (P.L. 87-868)

88th Congress

First Session

... Health Professions Educational Assistance Act of 1963 (P.L. 88-129)
... Mental Retardation Facilities and Community Mental Health Centers Act of 1963 (P.L. 88-164)

Second Session

... To increase the authorization for appropriations for the President's Committee on Employment of the Handicapped. (P.L. 88-321)
... Hill-Burton Act Amendments of 1964 (P.L. 88-443)
... Graduate Public Health Training Amendments of 1964 (P.L. 88-497)
... Nurse Training Act of 1964 (P.L. 581)

89th Congress

First Session

... National Technical Institute for the Deaf Act (P.L. 89-36)
... Drug Abuse Control Amendments of 1965 (P.L. 89-74)
... Mental Retardation Facilities and Community Mental Health Centers Construction Act Amendments of 1965 (P.L. 89-105)
... Community Health Services Extension Amendments of 1965 (P.L. 89-109)
... Health Research Facilities Amendments of 1965 (P.L. 89-115)
... Gorgas Memorial Laboratory (P.L. 89-181)
... Heart Disease, Cancer and Stroke Amendments of 1965 (P.L. 89-239)
... To amend the Act authorizing a loan service of captioned films for the Deaf (P.L. 89-258)
... Medical Library Assistance Act of 1965 (P.L. 89-291)
... Health Professions Educational Assistance Amendments of 1965 (P.L. 89-290)
... Vocational Rehabilitation Act Amendments of 1965 (P.L. 89-333)

Second Session

... Amendments to Sec. 402(d) of the Federal Food, Drug and Cosmetic Act (P.L. 89-477)
... Model Secondary School for the Deaf (P.L. 89-694)
... Veterinary Medical Education Act of 1966 (P.L. 89-709)
... Comprehensive Health Planning and Public Health Services Amendments of 1966 (P.L. 89-749)
... Allied Health Professions Personnel Training Act of 1966 (P.L. 89-751)

90th Congress

First Session

... Mental Health Amendments of 1967 (P.L. 90-31)
... Vocational Rehabilitation Amendments of 1967 (P.L. 90-99)
... Mental Retardation Amendments of 1967 (P.L. 90-170)
... Partnership for Health Amendments of 1967 (90-174)

Second Session

... Vocational Rehabilitation Amendments of 1968 (P.L. 90-391)
... Animal Drug Amendments of 1968 (P.L. 90-399)
... National Eye Institute (P.L. 90-489)
... Health Manpower Act of 1968 (P.L. 90-490)
... Health Services Act (P.L. 90-574)
... Radiation Control for Health and Safety Act of 1968 (P.L. 90-602)
... To amend the Food Drug and Cosmetic Act to increase the penalties for unlawful acts involving LSD and other depressant and stimulant drugs. (P.L. 90-639)

Patient Care Tasks in Connecticut Emergency Departments: Responsibility of Registered Nurses or Physicians?

Samuel B. Webb, Jr., Dr.P.H., and Gerald A. Starr, M.P.H.

Introduction

The ability of many general hospitals in the United States to meet the increased demand placed upon their emergency departments in the past decade has been the topic of many studies.[1-4] Though the problem is recognized, demand in a recent seven-year period increased 100 percent.[5] Moreover, this demand is not only in numbers but also in the range of services expected.[6] It is believed that basic to improvement of emergency department services is the training and upgrading of the personnel rendering these needed services.[4-7] Clearly, the proper personnel, appropriately trained and motivated, must be in the right place at the right time if quality emergency service is to be a reality. To achieve this, a number of questions need to be answered: What are the institutional goals and policies; and how important are emergency services within such priorities? What are the characteristics of the patients utilizing the emergency department? What is the role for a given category of personnel within the emergency department? What is the proper training for such roles? How many are needed? Where should they be placed? While there are many issues that need clarification before such questions can be answered definitively, one starting point is a knowledge of the patient care tasks presently being performed in emergency departments and the degree of acceptance of these tasks by people who have chosen to work in this area, namely, registered nurses and physicians.

Purpose and Method of Study

The purpose of this study is to characterize, analyze, and describe the various patient care tasks performed by professional personnel in the emergency departments in one state. In this manner it is believed that answers to some of the questions posed above can begin to be developed on an objective and meaningful basis.

To achieve this purpose, a detailed, structured, pre-coded questionnaire composed of primarily closed-end questions was sent to all 35 general hospitals in the state for distribution to registered nurses and physicians working in emergency departments on a full or part-time basis. The data gathered was then key-punched to facilitate computer analysis.

The several hospitals received a number of questionnaires equal to the number of stated registered nurses and physicians employed or working in their emergency department. A control form was completed for use in determining the number of questionnaires distributed and subsequently, the number of completed questionnaires returned. Distribution took place in the latter part of July, 1971 and no responses were accepted after October 1, 1971. The population at risk was 359 registered nurses of which 256 (71.3 percent) returned questionnaires, and 224 physicians of which 109 (48.7 percent) returned questionnaires suitable for analysis.[8]

No quantitative measures or scores could be developed to cause one task to fall in one category of personnel rather than another. For a task to be assigned to a registered nurse, there had to be a high percentage of responses from the physicians indicating a willingness to delegate the task, and a high percentage of responses from registered nurses indicating a willingness to perform the task. Tasks placed in the "disagreement group" are those which physicians indicated they would not delegate, although nurses reported willingness to perform them, or tasks that physicians reported willing to delegate but nurses felt were above their professional capabilities.

Findings

Table 1 presents a composite of emergency department patient care tasks performed in Connecticut (and undoubtedly most other) hospital emergency departments. Column 1 constitutes a large portion of routine tasks. These seem to be delegated more as a function of workload conditions or the availability of various levels of professional staff rather than well-defined levels of responsibility or professional capability.

Column 2 presents tasks customarily performed by physicians, although some disagreement about who should perform same is evident (see Column 4) and will be discussed later. As can be seen these tasks vary in degree of responsibility and skill required in their performance.

Column 3, registered nurse tasks, represents a fairly diverse combination of responses. Basically,

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TABLE 1

TASK ANALYSIS OF PATIENT CARE FUNCTIONS
PERFORMED BY REGISTERED NURSES AND PHYSICIANS IN CONNECTICUT EMERGENCY DEPARTMENTS
1971

(1) Tasks Performed By Both	(2) Tasks Performed By Physicians	(3) Tasks Performed By Nurses	Tasks About Which Disagreement Exists
1. Tape or bandage ankle, wrist, knee, or chest	1. Clean ears of impacted wax	1. Defibrillate cardiac patients	1. Remove foreign body from external ear
2. Apply sling	2. Remove foreign body from external ear	2. Pump stomach	2. Remove foreign body from nares
3. Apply splints to possible or untreated fractures or	3. Remove foreign body from nares	3. Clean ears of impacted wax	3. Suture superficial laceration
4. Apply finger or hand splint	4. Remove foreign body from eye	4. Remove sutures	4. Incision and drainage of small superficial abcess
5. Apply cervical collar	5. Control anterior nasal hemorrhage	5. Start an I.V.	5. Insert packing into incision wound or cavity
6. Stop minor bleeding	6. Suture superficial laceration		
7. Clean wounds, cuts, abrasions	7. Incision and drainage of small superficial abcesses		
8. Take and record vital signs	8. Insert packing into incision wound or cavity		
9. Insert oropharyngeal airway	9. Reduce simple fractures		
10. Perform IKG's	10. Casting procedures		
	11. Debride wounds or burns		
	12. Check incisions, wounds, or burns for healing progress		
	13. Perform tracheotomy		
	14. Administer local anesthetics		
	15. Perform history and physical examination		
	16. Order laboratory tests		
	17. Complete "return to work" permits		
	18. Perform endotracheal intubatiob		

SOURCE: Study Data

physicians indicated a willingness to delegate the specifically mentioned task to registered nurses and the nurse either already performed the task or was willing to, given the proper training. In some cases, however, a fairly high number of nurses (about 30 percent) felt that these tasks should be performed only by a physician. Interestingly, task No. 5 in Column 3, "Start an I.V.," showed a high degree of acceptance as a nursing function. However, few perform this at present due to lack of training.

Column 4 presents task situations in which there was disagreement between the nurse cohort and the physician cohort. Such disagreement flowed both ways, e.g., physicians were not willing to delegate or the nurses were not particularly eager to accept the responsibility. "Removals of a foreign body" presented a large degree of variation. Physicians seemed (although not unanimously) willing to delegate the task while the nurses were undecided, with almost equal numbers willing or unwilling to accept responsibility. The disagreement was more substantial concerning Tasks Nos. 3 to 5 in Column 4. While a large number of nurses were willing to undertake these tasks, physicians on the whole were not willing to impart the opportunity.

Conclusion

Now that emergency medical services are receiving nationwide scrutiny in professional journals and the lay press, it will not be surprising if some current emergency department roles and tasks for both physicians and nurses undergo change and evolution. This study indicates a relatively high degree of agreement between physicians and nurses regarding patient care tasks performed in the emergency departments of the state. Clearly, nurses seem willing and able to accept certain roles traditionally reserved for physicians just as physicians appear willing to delegate certain tasks. Some disagreement exists but it would not appear to be insurmountable. However, in order to be able to perform some functions, more training is necessary, such as nurses learning how to perform I.V.'s. It does seem a waste of existing resources to create new professions or even specialty groups within established professions when the existing training structure could re-orient itself to training existing professionals in mutually acceptable roles. When this occurs, it seems safe to say that in the emergency department not only will professional personnel be in the right place at the right time but they will be performing agreed upon roles. This should enhance the quality of emergency service as well as increase its efficiency and effectiveness.

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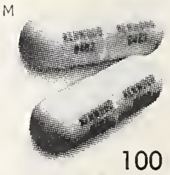

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Open Information and Medical Care: A Proposal for Reform

Budd Shenkin, M.D., and David C. Warner, Ph.D.

In a recent article[1] we proposed that patients should be routinely issued copies of all their medical records, both inpatient and outpatient. We argued that patients, physicians, and planners and administrators would all benefit from this change, since the conditions of open information and freedom of choice that prevail in the market would be introduced into the area of medical care. Here, we would like to recapitulate our arguments in brief, and relate some of the responses we have received.

Patients would come to know much more about their medical conditions, and their compliance with their physicians' recommendations would probably improve as a result. Care would be more continuous in emergency rooms when specialists were consulted, and when physicians had to be consulted away from home. Patients would be subjected to fewer repeat tests, would be required to repeat but little information, and would receive more complete and better informed care. They would have a greater capacity to exercise free choice. At present, the criteria for judging physician capability are limited and inaccessible to most patients. And patients are inhibited from freely changing physicians, in part, by the expense of new workups, and by the difficulty of ever returning to the original physician should the new one request the records. A patient's relationship with his physician would improve as unwarranted feelings of dependency could be reduced, and as patient familiarity with medical concepts could improve communication. Physicians would benefit as well. At present, they have only limited means of evaluating one another's performance. As a result, an incentive for practicing high-quality care is lost, and referring patients to other physicians of known competence is made more difficult. An effect of implementing our proposal would be the emergence of decentralized and voluntary peer review. After seeing several patients whom another practitioner had seen, in conjunction with their records, a physician could hardly help making an assessment of that physician's abilities and practice. In this way professional reputations would grow according to the concrete criteria of patient care. Anticipating this process, physicians would have a clear incentive to practice high-quality medicine, especially since the practices of the most reputable would probably increase. In many cases, favorable evaluation by a specialist of a primary practitioner's records, or vice-versa, would result in increased trust and more expeditious referral of the patient to the appropriate level.

The proposal would also provide physicians new opportunities to learn. Just as residents learn by caring for patients and observing how various specialists treat their patients after they themselves have done as much as they can, so physicians in whatever practice setting would have the same experience repeatedly. Furthermore, we think our proposal would make the practice of medicine more satisfying and fulfilling. Practitioners have recently become less satisfied with their role and status in society. One cause of discontent has been that professional prestige has centered around academic centers where scientific advances are made, and where articles published and rank achieved are convenient measuring rods. By contrast, practitioners have had happy patients and money to mark them as successful in the community at large, but these advantages have counted little within the profession. Two other sources of discontent have been specialization and discontinuity which have frustrated practitioners trying to provide for a patient's needs. Moreover, the strains in physician-patient relations have affected physicians probably even more than patients, since being a patient is only a part-time pursuit.

Decentralized peer review would ameliorate the strain. It would provide recognition of excellence in the practice of medicine, and hence enhance the prestige of being a practicing physician. Patient record and the care they reflected would become a source of pride open to the perusal of fellow professionals. The expected improvement in continuity would decrease frustrations, and improved physician-patient relations would add importantly to physician satisfaction.

Administrators and policy makers would be the third group of beneficiaries. They do not have the capacity easily to evaluate or control the appropriateness of medical care, nor have they been able to remedy such maladaptive forces as the drive for more and more physician specialization. Increasingly, they are turning to comprehensive organizational

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solutions that call for increased centralized decision making and an increase in provider aggregations, such as Health Maintenance Organizations, foundations for medical care, neighborhood health centers, hospital-based practices, Professional Standards Review Organizations, and comprehensive health planning. Most of these solutions would deliver more power to the prospers of reform.

Adopting the proposal would reduce fears about physician accountability and quality. Self-regulating, decentralized peer review would provide better individual assessments than centralized review, since reviewers could correlate the patient himself with the record, instead of merely checking its internal consistency. Both inpatient and outpatient records would be used, and information would be generated precisely at the points of usage—patients and colleague physicians. On the other hand, some functions of centralized peer review, such as standards setting, would not be pre-empted.

Physicians responding critically to the proposal have usually cited the inhibitions that would be placed upon their discretion. With the fatally ill patient or the suspected psychosomatic, they feel that enforced confrontation of the patient with these facts would be deleterious. We feel that although this might sometimes be true, the literature documents that terminal patients are most often treated quite inappropriately. Letting the patient know the truth overtly would be an overall improvement and would force family and physician to confront the problem openly, rather than denying it until it is too late to act. Clearly, however, this question should be investigated with empirical studies.

Both physicians and non-physicians objecting to the proposal have most often cited the probability of physicians evading the requirements. They feel that physicians would keep double records, use even more recondite circumlocations, and otherwise evade the requirements of full communication. We do not think this would happen, but this question, too, should be subject to investigation.

We have been surprised that our responses have been predominantly positive, not negative. Several practitioners have reported to us that they have been unilaterally sending their patients copies of their records. Although we believe that many of the benefits we foresee depend upon widespread adoption of the practice, none of our correspondents have reported dissatisfaction, although several have questioned the impact upon the patient. Documented experiments with the procedure at the Given Health Center at the University of Vermont, where the patient is given his own record to audit, have had positive results.[2] They found that 97% of the patients indicated less worry about their health after reviewing their record.

The proposal represents incremental rather than a comprehensive change; its implementation should improve medical care at once and exert a salutary influence on the system's continuing evolution. Despite the fact that the proposal promotes free communication and patient autonomy, it would not interfere with centralizing reforms, such as Health Maintenance Organizations and Professional Standards Review Organizations. On the contrary, autonomous influences are sometimes essential even with administered systems.

More specifically, countries with tightly organized medical-care systems tend to have different expectations in physician-patient relations—Sweden is a good example. If the United States is to evolve toward more formal organization, care will have to be taken to structure that system so that our own preference in physician-patient relations will be preserved (or resurrected). In addition, the United States has a traditional respect for family practitioners often lacking in other countries; we would be well advised to nurture this functional attitude. The proposal would contribute to preservation of both these positive qualities as our medical care system evolves.

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A Xenodochium for Apollo in the Temple of Asclepius

Stuart F. Spicker, Ph.D.

On the uppermost floor of the University of Connecticut Health Center's Lyman Maynard Stowe Library (dedicated to its first Dean of Medicine), and prior to the arrival of the new Director of the Medical library, overlooking a contemporary rendering of the ancient atrium gardens, an unobtrusive room was letterpressed with an equally obscurant "HISTORY OF MEDICINE." Upon entering one discovered the accommodation wanting in human vitality and, at best, unaccommodating even to those who might have been bent upon research in the history of the art and science of medicine and dental medicine. The immediate response was one of wonder, but not awe, for one could not help but perceive the dearth of volumes, bound in white buckram, preserved in handsome, auspicious and secure cabinets. The occasional visitor, especially if he or she has, on occasion, entertained scholarly pursuits, might be too quick to chastise those responsible for the plentifully-empty shelves. But that would be, paradoxically, to accuse too hastily on the basis of simple ignorance of the historical past, neglecting the facts of the historical situation which, when understood, quite readily explain and to some extent justify the paucity of the history of medicine collection.

There was a day, not too many years ago, especially at the medical school of Johns Hopkins University and a few others, when history of medicine flourished in the United States, when historians of medicine like Ludwig Edelstein and his contemporaries were in the ascendancy, and when the discipline itself captured the interest of medical faculty and not a few medical students, both graduate and undergraduate. Rather than undertake an elaborate exegesis of the decline of the impetus of that humanistic discipline, previously always welcome by physicians, students, and other health professionals, let it suffice to say that the rise of the social and behavioral sciences, soon after World War II, eclipsed the intellectual spotlight and commanded the attention of health professionals. Historians of medicine, though never evicted from their cloistered chambers by a pogrom initiated by entrenched men of medicine, were simply tolerated, for physicians and even medical administrators would not abandon their past, deny their own genesis, or reject their own heritage. After all, every initiate into the medical profession had to learn how to "take" a history; even if he never fully appreciated the biography of his healthy clientele, each physician in daily clinical practice never permitted himself to forget to "do" a history of systems, account to some degree for family and social history, and trace, to the extent possible, the course of the disease if not the *curriculum vitae* of the person who was ill. Carry-over from the past—the quite literal meaning of 'tradition'—tends to hold on with formidable strength not respecting the grandiose armamentarium of modern medical centers; this is straightforwardly reflected in rooms hidden away in the far recesses of contemporary libraries quite inconspicuously marked "HISTORY OF MEDICINE."

Only five years ago the journal of the American Academy of Arts and Sciences, *Daedalus*, devoted itself to the issue "The Future of the Humanities" (Summer, 1969) and nowhere in its pages was there any indication that the Humanities would in a short time make significant conceptual contact with Medicine. This is quite understandable and certainly no fault of the impetus behind this volume, James S. Ackerman, my friend and professor of fine arts at Harvard University. For one thing, the prior number of *Daedalus* (Spring, 1969) *was* devoted to the issue: "Ethical Aspects of Experimentation with Human Subjects," and my teacher, Hans Jonas, supplied the philosopher's perspective in his provocative article, "Philosophical Reflections on Experimenting with Human Subjects." The point is simply that in spite of growing awareness of the import of humanistic studies in medical education this movement was still dormant at the preconscious level (though never quite unconscious) and most of us did not suspect that a renaissance of a very special sort was about to take place within medical schools, health care institutions (including a few hospitals) and, not surprisingly, on American soil.

A cursory look at the history of The Humanities reveals that for second-century Rome there were nine liberal arts: grammar, logic, rhetoric, geometry, arithmetic, astronomy, music, architecture and medicine. By the fifth century, according to Capella, the latter two—architecture and medicine—were known as professional subjects. In the sixth century one spoke of the *trivium*—grammar, rhetoric and logic

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(dialectic), and the *quadrivium*—arithmetic, geometry, astronomy and music. Together, the meeting place of the three roads and the four roads composed the seven liberal arts.

In our time the National Endowment for the Humanities includes under the rubric of "The Humanities" the following disciplines: archaeology, languages (modern and classical), linguistics, literature, the history, criticism, theory and practice of the arts (painting, music, dance, sculpture and theatre). In addition, it lists philosophy, jurisprudence and history. Moreover, it acknowledges "those aspects of the social sciences that have humanistic content and employ humanistic methods." It is of interest to note that Medicine is no longer viewed as one of the liberal arts, in spite of a current taxonomy of knowledge which considers Medicine the most scientific of the humanities and the most humane of the biomedical sciences. Furthermore, due in great part to the radical bifurcation of Church and State, neither religion nor theology is listed among The Humanities by the Endowment; yet a strong case can be made (and I believe should be made) for viewing religion as countable among the humanistic disciplines. This is patently obvious to those who appreciate the intimacy between on-going medical education—which includes pastoral care along with clinical practice and the biomedical sciences—and the function of the University Hospital. Connecticut's University Hospital, for example, is appended to the educational complex (perhaps it is the other way around). Patient care necessitates the services of a wide group of persons devoted to the care of others, and such a group will include, in addition to medical and health science professionals, experienced chaplaincy who can, in addition, serve as members of the medical teaching faculty. Further, the myriad of newly-formulated questions which have arisen in our technological era and the technological conquest which impels the advance of medicine require articulate and critical intelligence in addition to the ability to perceive subtle distinctions as revealed in daily patient care in the actual hospital and other clinical settings. Again, philosophers, historians of medicine, and clergy professionally trained in biomedical ethics are being invited into the auspicious temples of Asclepius. Since hardly any moral issue in medicine can be critically formulated without recourse to jurisprudence and positive law, the notion of medicine in collaboration with the legal profession is also being acknowledged, but for reasons other than articulating the machinations of malpractice action and the specific interests of forensic medicine. That is to say, jurisprudence—one of the humanities according to the National Endowment—has an appropriate place along with philosophy, religion and history of medicine as itself a humanistic discipline. But such a claim is not particularly revelatory nor is it merely salutary, for those persons familiar with the course of medical education over the last few decades. The important point is that the integration of certain humanistic disciplines into medical education must itself take place within a context which permits them to modify function. And that is what has happened since behavioral and social scientists entered systematically into the framework and matrix of medical research and education. That is what is now beginning to happen as persons professionally credentialled in the humanistic disciplines are systematically assimilated into the medical cell by means of the more subtle process of intellectual osmosis.

At the Health Center philosophy and religion will initiate such a process; in time, as clarification of needs is manifest, jurisprudence, history of medicine, and literature will be added. Close cooperation between humanists, social scientists, and other health professionals is mandatory—the humanities easily intersect the set of interests of social and behavioral scientists, a fact recognized by the National Endowment for the Humanities.

In a recent issue of *The New England Journal of Medicine* (May 9, 1974), Dr. Edmund D. Pellegrino began an editorial with a reference to a new and unique program sponsored by the Endowment, a program designed for physicians who would devote a month to intensive study of philosophical issues or historical foundations of medicine or, in one case, medical ethics, depending on which seminar of three they would attend. At the Health Center a program designed to consider similar topics is currently being developed. The perpetuation of humanistic studies within the on-going biomedical and clinical programs will be introduced through the disciplines of philosophy and religion. The function of such studies is not singular.

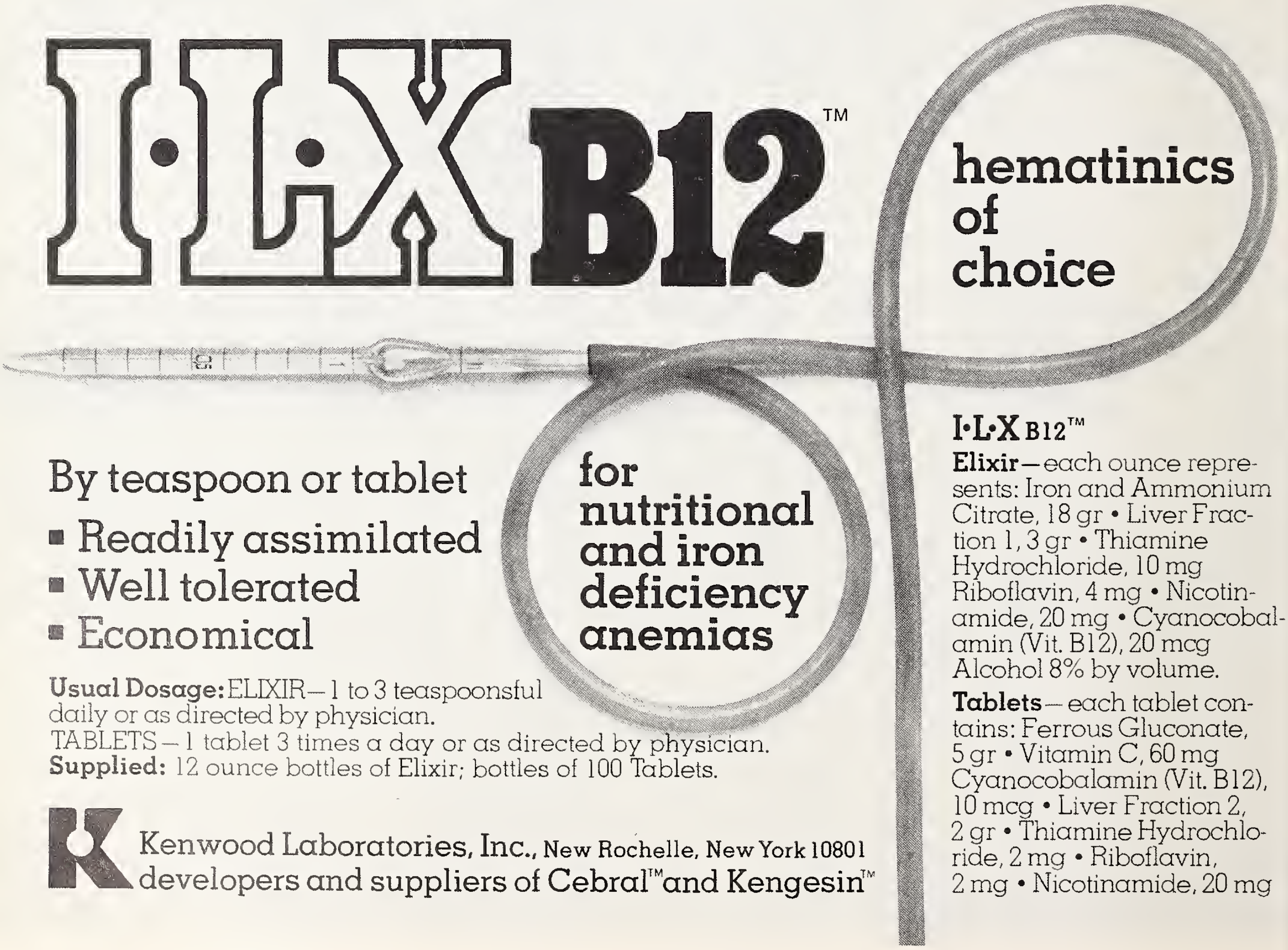
First, there is the teaching function, accomplished through seminars, plenary sessions (currently guided by "Subject Committees," a new term for interdisciplinary courses) and independent tutorial research. Twice during the forthcoming academic year a medical elective or "selective" will be offered to third and fourth year medical students—"Analyzing Ethical Issues in Medicine"—which may, one day, prove a suitable topic for seminar within a program of Continuing Education for practicing physicians in the State of Connecticut. In his editorial, Dr. Pellegrino remarks that an "obvious and even more urgent need is to bring the teaching of ethics and the humanities into the life of the mature practitioner through continuing education. Here," he adds, "the impact on the quality of medical decisions is much more immediate and direct. Practitioners are becoming increasingly sensitized to the complexities of the moral dilemmas inherent in the application of modern medical knowledge" (Vol. 290, No. 19, p. 1085). In addition, there is the graduate teaching function accomplished through such mechanisms as Medical Ethics Grand Rounds, rotating through the various clinical specialties and clerkships. In addition to the teaching function there is a research function.

Humanists are usually professional scholars in their own disciplines and their engagement with members of the medical profession calls for no less competent scholarship. One focus of such a function will be manifest in the Second Trans-Disciplinary Symposium on Philosophy and Medicine to be sponsored by our School of Medicine. Its principal theme will be The Philosophical Dimensions of the Neuro-Medical Sciences. The Second Symposium (the first was held this past May at the University of Texas Medical Branch in Galveston), will convene May 15-17, 1975, at the Health Center's Keller Auditorium. The *Proceedings* will appear as an annual series, *Philosophy and Medicine,* published by D. Reidel in Dordrecht, Holland. Soon a formal statement will announce a new *Journal of Medicine and Philosophy* which will present articles addressed to problems at the interface of these two formidable disciplines.

The service function of Humanistic Studies is, as with other programs and elements within medical education, often evinced by the participation of humanists on various committees. For example, humanists have a vital role to play in offering an additional perspective to committees which are responsible for reviewing research proposals which include, by design, the participation of human subjects; committees such as tumor boards which affect the lives of persons with carcinoma and, as with other persons experienced with the workings of academe, committees on graduate and undergraduate education can also benefit from the impact of academic humanist-educators. Such interactions between physicians and philosophers are relatively new in spite of a powerful tradition within Western culture which began with the ancient Greek philosopher-physicians, like Aristotle (4th century B.C.) or the Medieval Islamics like Avicenna, the author of the 11th century *Treatise on the Canon of Medicine,* who himself was succeeded by the eminent personage of Maimonides (Rabbi Moses ben Maimon) whose *Moses' Chapters*, written in the 12th century, contains an impressive critique of Galen; in addition, our tradition includes physician-philosophers like Julien Offray de La Mettrie the author of *L'Homme Machine* (1743) and the American, William James who, unbeknownst to many, received his doctor of medicine degree at Harvard in 1869. In our own century, we encounter, for example, Karl Jaspers, the author of *Allgemeine Psychopathologie*, as well as *Die grossen Philosophen* and innumerable other works. Such figures, appropriately discussed within a tradition of the history of medicine and history of philosophy, are not fully comprehensible from historical analyses alone, however. For history of medicine is *not* medicine and history of philosophy is *not* philosophy. Although Medicine and The Humanities must of necessity meet on ground *prepared* by historical understanding and sensitivity, the encounter at the interface of these disciplines reveals the need for a new synthesis. Both Medicine and The Humanities have been remiss in failing to discourse together; this is not only revealed in the profusion of medical literature, scholarly as well as "throw-away," but also is symptomatically revealed when one peruses *The Encyclopedia of Philosophy* in all eight volumes and nowhere discovers even in Volume V any rubric "Medicine." (Fortunately *Index Medicus* has the appropriate rubrics including, even to this writer's amazement, "Existentialism.")

Having said all of this from the standpoint of a biased participant, I should in all fairness offer the simple proof for the proposition that "humanistic studies in the medical setting cannot be done well, and therefore ought not to be attempted." It proceeds as follows: "A humanist is either a scientist or he is not a scientist. If he is not a scientist then he is unfit to do humanistic studies. If he is a scientist, then he ought to be doing something more important than humanistic studies." Such an "argument" is surely held by some health professionals if not actually promulgated. However, I am pleased to report, at this time, that plans for humanistic studies have not fallen afoul of this attitude, although here and there I'm certain that some medical faculty hold such a conclusion is true if not the admittedly weak premises themselves. But it is not a sound argument and it is, of course, invalid as arguments go. So much the worse, then, for those who propound the inference that humanists are either "unfit" or engaged in the "unimportant." It is not too difficult to pass between the horns of that dilemma. But proof of this claim itself necessitates engagement with the humanities on the part of those who make the claim, and that is all that is expected by philosophers, theologians, doctors of jurisprudence, and historians of medicine.

In summary, it may well be a propitious moment for Philosophy and the other Humanities, represented by the god Apollo, to be accepted as foreigners and offered the guest suite in the temple of Apollo's son, Asclepius, the god of healing and medicine. Ironically, PLATO already lives in the temple of Asclepius, under the guise of a fourth generation computer-based education system whose name is an acronym of Programmed Logic for Automated Teaching Operations. PLATO IV is designed to handle some 4,000 remote student terminals, almost half of the free population of Athens in the fifth-century B.C., a student population unimaginable to the most imaginative Greek philosophers, including Plato. Time, of course, will determine whether PLATO IV, the artifact, will be more welcome in the temple of Asclepius than Apollonians bearing the tradition of Western culture and offering to challenge the intellect of students of Asclepius. Whatever the outcome, some will be sensitive to the fact that Asclepius is one of the sons of Apollo. The son, preoccupied with healing and curing the ill, and caring for the infirm, graciously offers his guest, his father, shelter within his temple. Surely Asclepius recognizes his own father! To be undiscerning here is necessarily to foreshadow nothing less than tragedy . . . .



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Physician Education in the People's Republic of China

Ernest W. Saward, M.D.

In early 1971 a new era in Chinese-American relations began bringing to an end a score of years in which mutual visitation had been precluded. This was initiated as "Ping-Pong" diplomacy but was soon expanded so that first Mr. Kissinger and then in early 1972 President Nixon visited China. Following the latter visit and related to the agreements made between the heads of state, a set of exchanges were decided upon.

One such exchange designated was in the field of health. In October, 1972 ten Chinese physicians visited the United States for three weeks. An apparently reciprocal invitation from the China Medical Association was extended in the Summer of 1972 and ten rather diverse representatives of the broad field of health from America arrived in Peking on February 15, 1973 and departed that city on March 11. The entire visit was under the aegis of the China Medical Association and its provincial branches. This status as official guests made possible much that would be precluded from tourists or the self-invited for many things were visited that one would not otherwise know about.

A significant fragment of the content of the trip related to the education of health professionals in contemporary China and the new attitudes resultant from the Cultural Revolution. It is this part that is reflected in these comments. As in all other respects at this time, one is shown those institutions the hosts wish one to visit. If, for example, one saw medical schools in Shanghai and Canton, but not in Peking or Nanking despite requests, it is not felt that the hosts' decision was less than deliberate.

Chinese categories of health personnel are somewhat confusing to Westerners, with our emphasis on qualifications and licensure. Various categories of personnel are translated "doctors," from those who have been through a Western-style medical school to those who have had a few months of training at a county hospital with continuing on-the-job training while doing peasant work in the fields. This is a broad spectrum indeed. Somewhat confusing to the Westerner as well is the status and role of the traditional doctor.

It seems quite obvious that the bulk of traditional doctors receive their training by an apprenticeship method, but today there are organized traditional medical schools in China. We visited only one, which I would suppose to be the model, and it has yet to reach the third year of a three-year curriculum.

Western medicine and traditional medicine under the admonition of Chairman Mao of "letting the past help the present" and "the foreign help China," and his recent statement that traditional medicine is a vast storehouse of aid to the people obviously has led to an integration of these two forms of practice. A representative from the Ministry of Health told us that between 1927 and 1947 only 9,000 Western-trained physicians were graduated in China. Similarly, there were only 80,000 hospital beds, almost all of which were in cities. Peasants had none.

From this it is evident that China had to start in 1949 from an exceedingly low base. There were four policies adopted: first, that of serving the worker, peasant and soldier; second, an emphasis on preventive medicine; third, to unite Western and traditional medicine; fourth, to generate health service as a mass movement. In other words, to mobilize the people to fight disease themselves. This last policy took the form in 1952 of a mass campaign to wipe out pests—flies, mosquitoes, rats and bedbugs, as well as snails in the South, where they produced schistosomiasis.

This was a health movement not relying on physicians at all, but on the people who were asked to eliminate these pests, not merely control them. Furthermore, the people were mobilized in campaigns to eliminate smallpox, cholera, and plague, as well as tetanus and venereal disease. Drug addiction was simultaneously eliminated. It is clear that these have been very effective movements, impossible if reliance were placed solely on professionals.

From 1949 to the cultural revolution in 1967, 250,000 Western-style doctors were trained. The Western-type medical schools closed throughout China during the cultural revolution and are only now starting back into quantitative production. A vast program to train technicians in the health field was engaged in and produced approximately a half million of these, including midwives, laboratory and x-ray technicians and many other categories.

Not the least of these is the now famous "barefoot doctor." This name is applied to the urban health worker as well as to the peasant member of the production team. Basically he or she has three

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months of formal training, usually in a county or municipal hospital, and then continuing intermittent on-the-job training while he works if rural at his normal agricultural tasks. In areas that are neither rural nor suburban, in the cities, the barefoot doctor is usually a young woman who spends most of her time in health work, both health practice and health education. We were told there are 1,200,000 barefoot doctors in China now, and if they were distributed evenly, their ratio would be one to every 650 people.

The effective result of this wide-ranging category of personnel called doctor is that health services in their broad sense, including preventive measures and health education, are accessible and very widespread, if not universal, amongst the whole population.

During the cultural revolution Chairman Mao made a very clear statement that the emphasis of medicine should be on the rural areas. This dictum, plus the general reevaluation of all institutions—particularly educational institutions—produced a true revolution in the medical profession. The overwhelming majority of medical schools ceased to function, and from 1967 to 1971 there were no new fully qualified medical graduates. Teaching continued at the postgraduate level in the teaching and municipal hospitals of the large cities and at provincial hospitals.

Also during this period 140,000 medical workers went from the cities to the countryside. This migration included most of the urban specialists. While in the countryside they not only carried on health education of the population and training of the local health personnel but did field work with the peasants. The purpose of this was not only to get medical care into the countryside but to reeducate the highly trained technical professionals in the needs of the people. In each city where I went, I asked members of the local hosting organization, the provincial medical association officers, about their period in the countryside; and with only one exception they had all been on such an assignment.

Today, there is an elaborate program of rotating urban health teams to the countryside for consultation and teaching as well as for assignment of young graduates. The statement was made from the Ministry of Health that 70% of the new graduates go to rural areas, whereas this had been a very difficult problem to solve previously.

The National Health Ministry in Peking is a relatively small agency functioning chiefly in relation to the provincial level and with the three autonomous municipalities. The agency at the provincial level is called the Health Bureau. Under the provincial-level health bureaus, each of which is managed by a revolutionary committee, there are regional and county health bureaus. The various categories of general hospital relate to these levels of function. The medical colleges apparently relate to the provincial bureaus. Standards are set by the Central Ministry, but it was emphasized that they do not stress qualifications, but ideology and performance.

The Health Bureau encompasses not only medical care, health education, and the training of health personnel of all categories but the manufacture of pharmaceuticals, including herbal medicines, sanitation of the environment, water management, particularly of wells, the managements of toilets and night soil, the safety of chimneys and apparently even the planting of trees. China historically was deforested by its people but since the revolution there is every evidence of a very avid campaign to put abundant trees back into the landscape of China. The result is impressive. Everywhere one goes one sees these young trees between 10 and 15 years old and many nurseries growing young stock.

The training of the fully qualified Western-type doctor has undergone a profound change of emphasis with the cultural revolution. Shanghai medical school No. 2 was described as coming into existence in 1952 through an amalgamation of four schools that existed before the revolution and from a small start had grown by 1966, before the cultural revolution and its closing, to 3,000 students and a greatly expanding faculty and library. It reopened in 1971 for a trial run of its new curriculum, and took in its first class of 500 students for a new three-year curriculum in 1972. It has three faculties and four teaching hospitals containing 2,800 beds, which it controls and operates. The buildings of the medical school are for the preclinical (basic science) courses.

During the cultural revolution the school underwent the process called criticism, struggle and transformation. The curriculum was entirely revised. Selection of students was put on a new basis. Students who wish to go to medical school must apply to the organization for which they work, as well as to the medical school. Students are not accepted directly after middle school but must put in one or two years working with peasants or in factories.

Apparently the communes and factories have quotas from which they may make recommendations. The student is chosen by his fellow workers for his ability to do the work, for the way he related to others at work, and for his political ideology. Of those recommended to the medical school, there is then a selection. There are approximately five applications with the necessary recommendations for every position in the medical school. The individual, male or female, must be between 20 and 22 years of age, and except under very unusual conditions, not married. An applicant must be a graduate of the middle school, and here grades become important. The medical school takes into account, however, not only the grades but recommendations from the work experience.

At least 10% of the entering class has had a health working experience such as being a barefoot doctor, nurse or other paraprofessional. Incidentally, though there has been health training for this segment of the entering class, they are not admitted with any advanced standing. It is also quite clear that some of the candidates, both men and women, come from the People's Liberation Army and continue to wear their uniforms while attending medical school. To be admitted to the People's Liberation Army in China is an honor to be sought after.

We asked whether a married candidate would be accepted in medical school and were told flatly "no," and it was implied that he would jeopardize his standing in medical school to be married while in medical training. It would show that he did not have a full understanding of the privilege he was being afforded by his fellow workers.

Before the Cultural Revolution the curriculum of medical schools was six or seven years. At the present time the curriculum is three or three and one-half years. The latter is said to be a three-year curriculum of medical school with a one-half year preparatory period in mathematics, foreign language, and physical science to bring the group to a uniform standard after their diverse careers as peasants and factory workers.

The first-year curriculum has, by title at least, the same subject content as the first two years of the typical U.S. medical school, with a constant stress upon the practical application of the material being presented. This curriculum is taught basically at the medical school campus, with a four-to six-week experience in the field for both faculty and students. The field experience apparently stresses infectious disease epidemiology and public health measures.

The second year is hospital based and represents continuation and application of microbiology and pathology, as well as physical diagnosis and the clinical clerkship (contact with patients). The third year is also hospital based and appears to be somewhere between the clinical clerkship and the internship, again with a considerable amount of didactic material and concomitant clinical responsibility.

A medical school year is divided into trimesters. I made the mistake of asking how long each trimester was and was met with the response, as if to an imbecilic question, that of course it was four months. The answer to a query about electives and elective time was that there is a free hour in every day.

There seems to be little question that the selection process of getting into medical school has assured that the student body will be free of the uncommitted, and only the most hard working, as well as the brightest, will have been admitted. Grades are given on a straight percentage basis. One is allowed to be failing in one course but not two. Apparently, however, this latter circumstance is exceedingly rare, because considerable help is available from fellow students as well as from faculty.

Illness can delay one up to one year, but after that period he is dropped from medical school. During the entire course of medical school, there is apparently some time devoted to ideological instruction. Inquiry as to career choice following medical school elicits the response that this is entirely a matter of the people's need, and one is assigned accordingly—primarily to various hospital levels throughout the country.

In response to the question of what would one do if he felt very strongly about wanting to be a surgeon and there was not a need for training as a surgeon, the answer was one would not have a strong feeling about being a surgeon under these conditions if he had been properly educated.

All in all, the three years of medical school are highly intensive, and together with the preparatory six months of equalizing education before medical school probably does not leave the 23- or 24-year old Chinese at any great disadvantage in understanding the technical concepts of contemporary medicine. In addition, he has been highly motivated to serve the people with the knowledge gained. The constant combination of theoretical and practical application is a break with the prior Chinese tradition of an initially long period of theoretical education. The Chairman of the Revolutionary Committee of the medical school, the person we would normally call the Dean, said that they had previously been force-fed like the Peking duck. The ratio of teachers to students in the medical school was one to six.

Postgraduate education did not seem as clearly defined or as formalized as in the United States. However, the young hospital physicians who would correspond to senior resident or junior faculty member seemed to have acquired much the same set of skills as their Western counterparts. The initial work assignment after graduation from the Western type medical school apparently lasts approximately three years, following which, depending on need as much as request of the individual, he may be assigned to a large hospital for a specialized service such as cardiology, orthopedics, the management of burns, etc. This may or may not involve organized study classes as well.

Clinical research appears to be an integral part of the work of the large municipal hospitals, but certainly not at the level of the neighborhood hospital or of the commune hospital. In addition there are separate research institutes in the major population centers. In Peking we visited one for tuberculosis and another for cardiovascular disease and in Shanghai, one for physiology.

There is a special department for the administration of research that serves both the research institutes and the hospital. For example, the Shanghai Institute of Research in Hypertension is in a teaching hospital but under a special administration for research evidently separate from the ordinary hospital administration.

The purpose of the abbreviated medical education compared to what existed before the cultural revolution is quite clearly to meet the needs of the country. The present curriculum is regarded as an experiment which has not been operative long enough to be evaluated. It would appear that discussion of the curriculum is ongoing. The present method of selecting medical students is felt by the faculty not to have impaired their scholastic caliber but to have enhanced their general knowledge and awareness of society. The closing of the medical schools for the approximately four years of the cultural revolution was felt not to have contributed to the doctor shortage but in fact to have greatly enhanced the number of various levels of medical personnel in the countryside because of the training afforded to those in the countryside. By placing the urban medical faculties in rural settings, the authorities made medical skill far more accessible than it previously was for the majority of the people.

Administration of the medical school is under what is called the unified leadership of the party and the revolutionary committee, and the administration is divided into (1) education and curriculum; (2) clinical work and research; (3) personnel working in the medical center; (4) health education and propaganda; and (5) logistics and supply. A secondary level represents the preclinical departments and the faculty of the teaching hospital, each having a committee with subsets of the five prior classifications in each. The third and last level is departmental by subject matter, but there are no departmental revolutionary committees.

It is interesting to hear that the "masses" who recommend the students from the work place are delighted with their new function and are in no sense frivolous in their selection but take pride in recommending only the very best for higher education. If their recommended student is chosen by the medical school, he receives gifts from his place of work, and his fellow workers are constantly informed as to his progress in medical school. Inasmuch as these chosen students were the best workers and most ideologically committed of the workers from the farm or factory, they are ideologically active in organizing the medical school and providing input into the curriculum.

All expenses in medical school are borne by the State.

It is interesting to an American that the foreign language taught in medical school is almost uniformly English, and the students are eager to practice it.

The multiple affiliated hospitals are administered and operated financially as one with the medical school. There is no separate hospital administration. Some medical schools teach administrative medicine, but apparently this is the exception rather than the rule. Each student gets precisely the same course content while in medical school. Career mobility exists, but it dies not shorten the time in medical school.

China has undergone a vast alteration since the present government came to power 23 years ago. This is naturally reflected in the concern for health. Starting from an abyss of neglect of ordinary citizens' health in the first half of the century due to revolution, civil war, foreign occupation and most of all, a government unresponsive to the need of peasants and workers, we see at present a very different orientation. "Serve the people" is the slogan and social relevance the order of the day. Without describing the organization of personal and public health services the discussion of training of health personnel may seem an isolated topic. But the flavor of the latter gives some idea of the attitude towards health service in general. It is with this reservation that a review of this training is described.

China is an ancient and sophisticated country. In a score of years it has had a profound socialist revolution that is still in transition. A visitor of only 24 days, despite prior study, finds continuing surprises up to the very last day. It is hoped that despite clear recognition of this limitation that some sense of the current activity in medical education is conveyed to those interested.

Distribution of Physicians in Connecticut by Comprehensive Health Planning Area and Individual and Contiguous Towns, 1973

Sarah S. Hirakis, M.P.H., and Norman L. Armondino

Introduction

The data presented in this study provides an updating of information previously included in *Connecticut Health Bulletin* articles on physician distribution in May and June, 1972 issues.[1] [2] The previous analyses considered only physician per population ratios for towns and areas. The current analysis, in addition to updating previous data, also considers physician per population situations of individual towns with situations of contiguous towns taken into account by developing a contiguous town ratio for each town in Connecticut. It is felt that the contiguous town ratios provide a more meaningful index of physician availability to residents of a particular town than an individual town ratio which does not consider physician availability in nearby towns.

The Data

Source data was obtained from the Connecticut State Department of Health. Physician data was provided by the Licensure and Registration Section while population estimates were made by the Public Health Statistics Section. Physician data include all active physicians registered in Connecticut as of July 1, 1973 by town of practice as determined from data cards submitted to the Licensure and Registration Section in the licensure process.

Contiguous towns were based strictly on adjoining borders. All towns which shared any part of a town line with an adjacent town were considered contiguous even if the common border only represented sharing a common corner. Conversely, no towns were considered contiguous, regardless of town line proximity, unless at least a common border point was shared.

Shortage Areas

Asterisks which appear at the left of town names indicate those towns with contiguous town physician per population ratios below .67 physicians per 1,000 population. The Bureau of Health Resources Development of the Public Health Service, U.S. Department of Health, Education, and Welfare considers areas with less than .67 physicians per 1,000 population as physician shortage areas and allows physicians practicing in these areas to apply for cancellation of a portion of educational loans made under the Health Profession Student Loan Program.*

Town Data

The data is presented by town for each of the eleven comprehensive health planning areas in the following tables.

TABLE 1

CAPITOL REGION COMPREHENSIVE HEALTH PLANNING AREA
DISTRIBUTION OF PHYSICIANS BY INDIVIDUAL AND CONTIGUOUS TOWNS, 1973

	Individual Town			Individual and Contiguous Towns		
Town	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*
*Andover	2,100	0	.00	22,000	3	.14
Avon	9,100	11	1.21	141,800	172	1.21
Berlin	14,900	7	.47	265,800	430	1.62
Bloomfield	19,700	17	.86	297,900	961	3.23
Bolton	3,700	0	.00	118,600	142	1.20
Bristol	55,800	57	1.02	149,100	117	.79
Burlington	4,400	0	.00	110,600	107	.97

*Contiguous Town Physician per Population ratio below .67 per 1,000

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**Additional detail regarding this provision is described in the handbook entitled* Entering an Agreement to Practice in a Shortage Area *which may be obtained from the following address: Student Assistance Section, Bureau of Health Resources Development, Health Resources Administration, Public Health Services, Department of Health, Education, and Welfare, Bethesda, Maryland 20014.*

TABLE 1 (Cont.)

CAPITOL REGION COMPREHENSIVE HEALTH PLANNING AREA

	Individual Town			Individual and Contiguous Towns		
Town	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*
*Canton	7,000	2	.29	52,700	28	.53
*East Granby	3,900	1	.26	97,300	56	.58
East Hartford	55,400	34	.61	324,500	964	2.97
*East Windsor	8,600	0	.00	116,800	50	.43
*Ellington	8,300	0	.00	136,100	76	.56
*Enfield	46,000	23	.50	94,200	37	.39
Farmington	15,000	30	2.00	275,300	393	1.43
Glastonbury	22,300	15	.67	200,200	198	.99
*Granby	6,500	2	.31	50,100	19	.38
Hartford	155,300	803	5.17	236,000	1,035	4.39
Hartland	1,400	0	.00	22,700	24	1.06
*Hebron	4,600	1	.22	50,700	20	.39
Manchester	48,600	90	1.85	174,600	178	1.02
*Marlborough	3,500	1	.29	45,100	21	.47
New Britain	79,600	146	1.83	187,100	247	1.32
Newington	27,400	41	1.50	397,500	1,162	2.92
Plainville	16,700	7	.42	200,600	256	1.28
Plymouth	10,600	4	.38	206,600	257	1.24
Rocky Hill	10,800	17	1.57	110,300	108	.98
Simsbury	19,300	11	.57	65,500	44	.67
*Somers	6,700	6	.90	70,600	35	.50
Southington	33,500	16	.48	290,000	345	1.19
South Windsor	15,700	5	.32	344,100	983	2.86
*Stafford	9,600	6	.63	28,980	13	.45
*Suffield	9,700	3	.31	81,000	34	.42
Tolland	8,400	1	.12	76,100	60	.79
*Union	480	0	.00	22,230	10	.45
Vernon	28,900	34	1.18	122,000	132	1.08
West Hartford	67,300	101	1.50	293,800	1,003	3.41
Wethersfield	27,200	17	.63	298,400	927	3.11
Windsor	23,300	17	.73	241,400	848	3.51
*Windsor Locks	14,900	5	.34	106,400	49	.46
Total	906,180	1,531	1.69			

*Contiguous Town Physician per Population ratio below .67 per 1,000

TABLE 2

CENTRAL NAUGATUCK VALLEY COMPREHENSIVE HEALTH PLANNING AREA DISTRIBUTION OF PHYSICIANS BY INDIVIDUAL AND CONTIGUOUS TOWNS, 1973

	Individual Town			Individual and Contiguous Towns		
Town	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*
*Beacon Falls	3,800	0	.00	50,400	20	.40
Bethlehem	2,000	0	.00	32,500	24	.74
Cheshire	20,100	19	.95	331,500	392	1.18
Middlebury	5,900	6	1.02	179,100	238	1.33
Naugatuck	24,100	10	.42	161,300	211	1.31
Prospect	6,600	4	.61	166,700	224	1.34
Southbury	6,900	20	2.90	43,000	75	1.74
Thomaston	6,300	5	.79	161,700	211	1.31
Waterbury	111,800	187	1.67	217,700	246	1.13
Watertown	19,200	8	.42	160,600	219	1.36
Wolcott	13,100	3	.23	244,900	286	1.17
Woodbury	6,200	7	1.13	44,800	51	1.14
Total	226,000	269	1.19			

TABLE 3

GREATER BRIDGEPORT COMPREHENSIVE HEALTH PLANNING AREA
DISTRIBUTION OF PHYSICIANS BY INDIVIDUAL AND CONTIGUOUS TOWNS, 1973

	Individual Town			Individual and Contiguous Towns		
Town	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*
Bridgeport	155,500	333	2.14	297,500	454	1.53
Easton	5,600	4	.71	141,800	146	1.03
Fairfield	58,400	75	1.28	290,300	513	1.77
Monroe	12,800	2	.16	101,700	74	.73
Stratford	49,700	29	.58	319,300	442	1.38
Trumbull	33,900	17	.50	344,000	472	1.37
Total	315,900	460	1.46			

TABLE 4

HOUSATONIC VALLEY COMPREHENSIVE HEALTH PLANNING AREA
DISTRIBUTION OF PHYSICIANS BY INDIVIDUAL AND CONTIGUOUS TOWNS, 1973

	Individual Town			Individual and Contiguous Towns		
Town	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*
Bethel	12,200	5	.41	100,600	162	1.61
Bridgewater	1,400	2	1.43	52,400	90	1.72
Brookfield	10,700	6	.56	110,300	169	1.53
Danbury	55,000	110	2.00	112,000	145	1.30
New Fairfield	8,300	4	.48	91,400	143	1.57
New Milford	15,800	22	1.39	44,400	48	1.08
Newtown	16,300	39	2.39	77,300	80	1.04
Redding	6,400	2	.31	139,200	198	1.42
Ridgefield	19,400	18	.93	96,700	143	1.48
Roxbury	1,300	1	.77	34,900	61	1.75
Sherman	1,600	1	.63	27,700	30	1.08
Washington	3,300	9	2.73	40,710	49	1.20
Total	151,700	219	1.44			

TABLE 5

LITCHFIELD HILLS-NORTHWESTERN COMPREHENSIVE HEALTH PLANNING AREA DISTRIBUTION OF PHYSICIANS BY INDIVIDUAL AND CONTIGUOUS TOWNS, 1973

	Individual Town			Individual and Contiguous Towns		
Town	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*
Barkhamsted	2,300	0	.00	66,100	80	1.21
Canaan	970	3	3.09	14,870	38	2.56
Colebrook	1,000	1	1.00	18,300	25	1.37
Cornwall	1,200	1	.83	22,080	48	2.17
Goshen	1,500	0	.00	57,880	87	1.50
Harwinton	4,600	1	.22	69,700	70	1.00
Kent	2,000	3	1.50	27,210	60	2.21
Litchfield	7,400	6	.81	78,510	83	1.06
Morris	1,800	0	.00	40,000	28	.70
New Hartford	4,100	2	.49	66,200	78	1.18
Norfolk	2,100	3	1.43	21,370	29	1.36
North Canaan	3,100	0	.00	9,770	14	1.43
Salisbury	3,600	8	2.22	11,270	35	3.11
Sharon	2,400	23	9.58	10,170	38	3.74
Torrington	32,300	52	1.61	63,700	82	1.29
Warren	910	1	1.10	16,310	20	1.23
Winchester	11,500	21	1.83	54,800	79	1.44
Total	82,780	125	1.51			

TABLE 6

MERIDEN-WALLINGFORD COMPREHENSIVE HEALTH PLANNING AREA DISTRIBUTION OF PHYSICIANS BY INDIVIDUAL AND CONTIGUOUS TOWNS, 1973

	Individual Town			Individual and Contiguous Towns		
Town	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*
Meriden	56,300	90	1.60	200,500	263	1.31
Wallingford	35,900	29	.81	205,100	196	.96
Total	92.200	119	1.29			

TABLE 7

MIDSTATE CONNECTICUT RIVER ESTUARY COMPREHENSIVE HEALTH PLANNING AREA DISTRIBUTION OF PHYSICIANS BY INDIVIDUAL AND CONTIGUOUS TOWNS, 1973

	Individual Town			Individual and Contiguous Towns		
Town	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*
Chester	3,100	3	.97	21,700	17	.78
*Clinton	10,800	4	.37	33,200	18	.54
Cromwell	7,700	11	1.43	100,000	162	1.62
Deep River	3,900	2	.51	20,700	26	1.26
Durham	4,700	0	.00	124,900	166	1.33
*East Haddam	4,900	3	.61	31,300	17	.54
East Hampton	7,700	2	.26	95,200	139	1.46
Essex	5,100	15	2.94	29,000	34	1.17
Haddam	5,500	4	.73	64,300	116	1.80
*Killingworth	2,800	2	.71	46,500	25	.54
Middlefield	4,200	0	.00	136,700	221	1.62
Middletown	35,600	102	2.87	145,300	226	1.56
Old Saybrook	8,900	10	1.12	25,100	32	1.28
Portland	8,700	10	1.15	82,000	140	1.71
Westbrook	4,300	1	.23	35,800	34	.95
Total	117,900	169	1.43			

*Contiguous Town Physician per Population Ratio Below .67 per 1,000.

TABLE 8

SOUTH CENTRAL CONNECTICUT COMPREHENSIVE HEALTH PLANNING AREA DISTRIBUTION OF PHYSICIANS BY INDIVIDUAL AND CONTIGUOUS TOWNS, 1973

	Individual Town			Individual and Contiguous Towns		
Town	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*
Ansonia	21,200	11	.52	69,400	84	1.21
Bethany	4,100	4	.98	130,400	96	.74
Branford	21,300	20	.94	70,800	47	.66
Derby	12,200	43	3.53	97,500	96	.99
East Haven	24,700	7	.28	213,700	899	4.21
Guilford	13,600	18	1.32	62,200	49	.79
Hamden	50,100	40	.80	274,900	975	3.55
Madison	11,400	9	.79	43,300	33	.76
Milford	52,100	51	.98	197,100	165	.84
New Haven	133,900	854	6.38	306,700	1,003	3.27
North Branford	11,200	2	.18	134,000	92	.69
North Haven	22,600	16	.71	278,400	948	3.41
Orange	14,400	11	.76	301,700	1,046	3.47
Oxford	5,000	0	.00	116,300	95	.82
Seymour	13,400	6	.45	96,000	89	.93
Shelton	28,100	12	.43	221,600	171	.77
West Haven	52,800	62	1.17	253,200	978	3.86
Woodbridge	8,200	13	1.59	257,500	982	3.81
Total	500,300	1,179	2.36			

TABLE 9

SOUTHEASTERN CONNECTICUT COMPREHENSIVE HEALTH PLANNING AREA
DISTRIBUTION OF PHYSICIANS BY INDIVIDUAL AND CONTIGUOUS TOWNS, 1973

	Individual Town			Individual and Contiguous Towns		
Town	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*
Bozrah	2,200	0	.00	76,600	113	1.48
*Colchester	7,000	2	.29	35,800	10	.28
*East Lyme	12,300	5	.41	54,900	20	.36
Franklin	1,400	0	.00	76,490	149	1.95
*Griswold	8,000	2	.25	35,500	9	.25
Groton	38,000	23	.61	117,900	133	1.13
*Ledyard	15,000	3	.20	111,200	38	.34
Lisbon	3,100	0	.00	64,500	109	1.69
Lyme	1,500	3	2.00	46,600	44	.94
Montville	16,500	3	.18	112,700	124	1.10
New London	30,900	98	3.17	86,600	127	1.47
*North Stonington	3,900	0	.00	48,500	8	.16
Norwich	43,600	107	2.45	73,700	110	1.49
Old Lyme	5,300	3	.57	33,100	36	1.09
Preston	3,800	0	.00	93,900	115	1.23
*Salem	1,600	0	.00	50,300	17	.34
Sprague	3,100	0	.00	75,990	148	1.95
*Stonington	16,300	3	.18	73,200	29	.40
*Voluntown	1,500	0	.00	27,600	9	.33
Waterford	17,700	6	.34	130,400	138	1.06
Total	232,700	258	1.11			

*Contiguous Town Physician per Population Ratio Below .67 per 1,000

TABLE 10

SOUTHWESTERN CONNECTICUT COMPREHENSIVE HEALTH PLANNING AREA
DISTRIBUTION OF PHYSICIANS BY INDIVIDUAL AND CONTIGUOUS TOWNS, 1973

	Individual Town			Individual and Contiguous Towns		
Town	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*
Darien	21,400	26	1.22	230,000	413	1.80
Greenwich	61,600	154	2.50	169,700	364	2.15
New Canaan	18,500	34	1.84	245,900	426	1.73
Norwalk	82,000	143	1.74	166,300	293	1.76
Stamford	108,100	210	1.94	209,600	424	2.02
Weston	8,400	7	.83	123,200	178	1.45
Westport	28,500	77	2.70	193,200	315	1.63
Wilton	15,900	13	.82	179,100	294	1.64
Total	344,400	664	1.93			

TABLE 11

WINDHAM NORTHEASTERN COMPREHENSIVE HEALTH PLANNING AREA DISTRIBUTION OF PHYSICIANS BY INDIVIDUAL AND CONTIGUOUS TOWNS, 1973

	Individual Town			Individual and Contiguous Towns		
Town	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population*
Ashford	2,400	0	.00	27,530	23	.84
*Brooklyn	5,200	0	.00	38,700	20	.52
*Canterbury	2,900	0	.00	36,690	10	.27
Chaplin	1,600	0	.00	46,140	64	1.39
Columbia	3,200	0	.00	43,500	45	1.03
Coventry	8,400	2	.24	97,700	101	1.03
*Eastford	950	0	.00	13,930	6	.43
*Hampton	1,100	1	.91	15,240	3	.20
Killingly	14,700	10	.68	45,200	37	.82
Lebanon	4,300	1	.23	45,200	45	1.00
Mansfield	18,200	22	1.21	63,800	67	1.05
*Plainfield	12,300	7	.57	46,500	19	.41
Pomfret	2,500	2	.80	37,950	34	.90
Putnam	8,600	18	2.09	38,600	38	.98
Scotland	990	0	.00	31,990	42	1.31
*Sterline	1,900	0	.00	30,400	17	.56
Thompson	7,900	5	.63	21,400	26	1.22
*Willington	3,900	1	.26	59,680	32	.54
Windham	20,900	41	1.96	62,090	66	1.06
Woodstock	4,900	3	.61	25,330	28	1.11
Total	126,840	113	.89			

*Contiguous Town Physician per Population Ratio Below .67 per 1,000

Shortage areas based on the less than .67 physician per 1,000 population criteria are as follows for towns within each Comprehensive Health Planning Area:

CHP Area	*Town*	*Contiguous Town Physician per 1,000 Population Ratio—*
Capitol	Andover	.14
	Canton	.53
	East Granby	.58
	East Windsor	.43
	Ellington	.56
	Enfield	.39
	Granby	.38
	Hebron	.39
	Marlborough	.47
	Somers	.50
	Stafford	.45
	Suffield	.42
	Union	.45
	Windsor Locks	.46
Central Naugatuck	Beacon Falls	.40
Greater Bridgeport	None	
Housatonic Valley	None	
Litchfield Hills	None	
Meriden-Wallingford	None	
Midstate	Clinton	.54
	East Haddam	.54
	Killingworth	.54
South Central	None	
Southeastern	Colchester	.28
	East Lyme	.36
	Griswold	.25
	Ledyard	.34
	North Stonington	.16
	Salem	.34
	Stonington	.40
	Voluntown	.33
Southwestern	None	
Windham Northeastern	Brooklyn	.52
	Canterbury	.27
	Eastford	.43
	Hampton	.20
	Plainfield	.41
	Sterling	.56
	Willington	.54

Comprehensive Health Planning Area Data

The Comprehensive Health Planning area ratios appear in Table 12 and are presented graphically in Figure 1. The 1971 physician per population ratios obtained from the previous studies referred to in the Introduction are also presented so comparisons of changes over time can be made.

TABLE 12

DISTRIBUTION OF PHYSICIANS BY COMPREHENSIVE HEALTH PLANNING AREA, 1973

CHP Area	*Population Estimate as of July 1, 1973*	*Number of Physicians*	*Physicians per 1,000 Population 1973*	*Area Rank 1973*	*Physicians per 1,000 Population 1971*	*Area Rank 1971*
Capitol	906,180	1,531	1.69	3	1.68	3
Central Naugatuck	226,000	269	1.19	9	1.10	10
Greater Bridgeport	315,900	460	1.46	5	1.48	4
Housatonic Valley	151,700	219	1.44	6	1.41	6
Litchfield Hills Northwestern	82,780	125	1.51	4	1.44	5
Meriden-Wallingford	92,200	119	1.39	8	1.34	7
Midstate	117,900	169	1.43	7	1.27	8
South Central	500,300	1,179	2.36	1	2.70	1
Southeastern	232,700	258	1.11	10	1.15	9
Southwestern	344,400	664	1.93	2	1.94	2
Windham Northeastern	126,840	113	.89	11	.75	11
Connecticut	3,096,900*	5,106	1.65		1.69	

*Total does not include 11,100 inmates of institutions.

Results

No Comprehensive Health Planning area in Connecticut was found to have a 1973 physician per population ratio of less than the H.E.W. shortage ratio of .67 per 1,000.

Physician per population ratios varied from a Windham Northeastern area low of .89 per 1,000 to a South Central area high of 2.36 per 1,000. The 1973 state ratio was 1.65 physicians per 1,000 population.

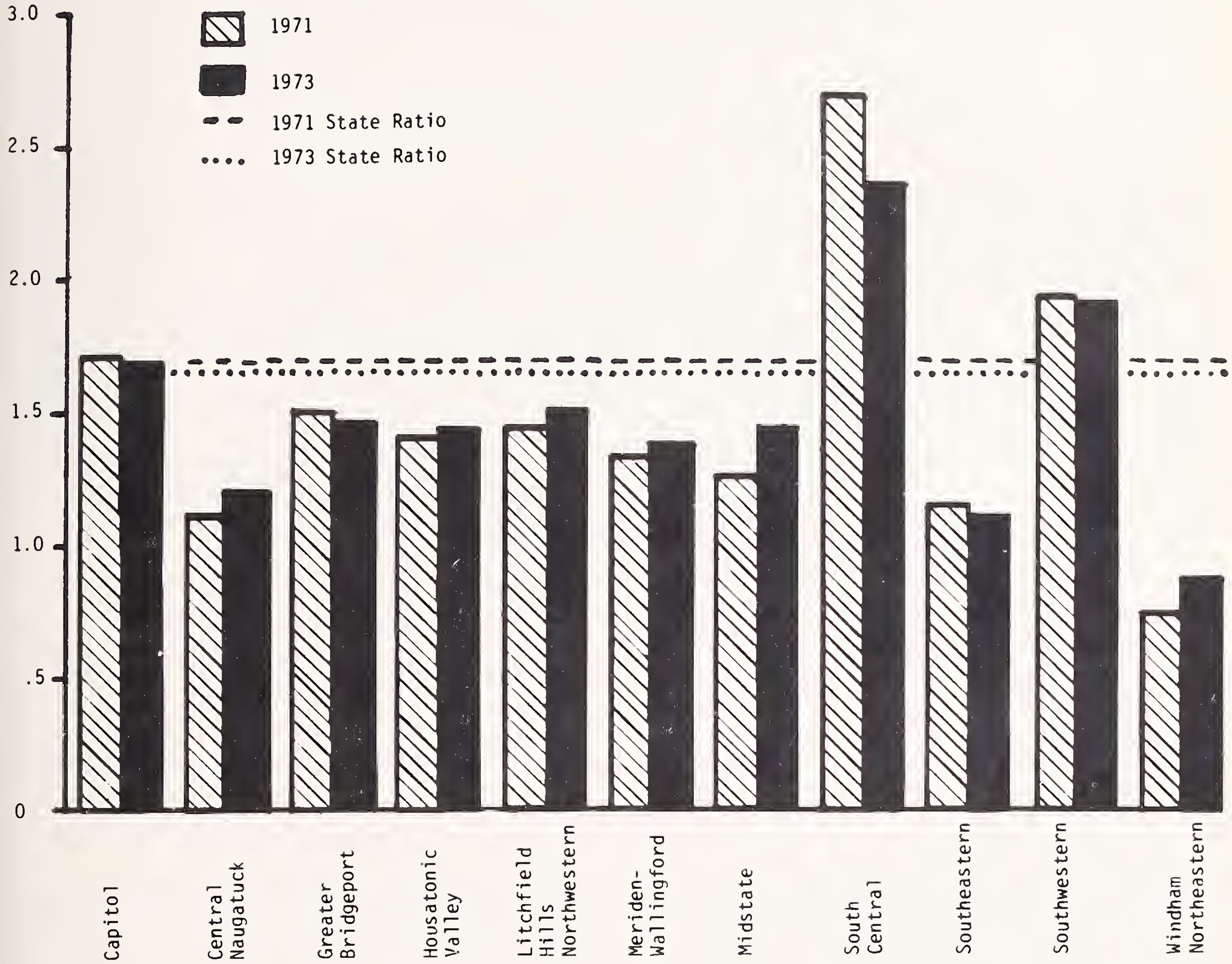
As is evident in Figure 1, changes in physician per population ratios between 1971 and 1973 were only slight in most areas and for the state as a whole. The 1971 statewide ratio was 1.69 physicians per 1,000 population while the 1973 ratio was 1.65. The most notable changes occurred in the extreme ratio areas of South Central and Windham Northeastern with the Windham area ratio increasing from .75 per 1,000 in 1971 to .89 in 1973 while the South Central area ratio decreased from 2.70 per 1,000 in 1971 to 2.36 in 1973. While both moved closer to the state average in 1973 than in 1971 the South Central area maintained the highest area ratio while the Windham Northeastern area maintained the lowest area ratio as was found in 1971 data. The greatest change found among the other areas involved a Midstate area increase from 1.27 physicians per 1,000 population in 1971 to 1.43 per 1,000 in 1973. As a result of this increase the Midstate area ratio ranked 7 among the 11 areas in 1973 as opposed to 8 in 1971. As indicated in Table 12, other areas also ranked higher or lower in 1973 than in 1971 but rank changes of no areas were more than 1 position and rank changes were the result of only slight ratio changes.

Within areas, the Capitol, Central Naugatuck, Midstate, Southeastern and Windham Northeastern areas were found to contain towns with contiguous town physician per population ratios below the shortage criteria. With the exception of one shortage town in the Central Naugatuck area and three in the Midstate area the remaining twenty-nine towns with shortages were found to be concentrated in the North-Central and Eastern portions of the state.

The 1973 statewide data reveals that Connecticut with a statewide ratio of 1.65 physicians per 1,000

FIGURE I

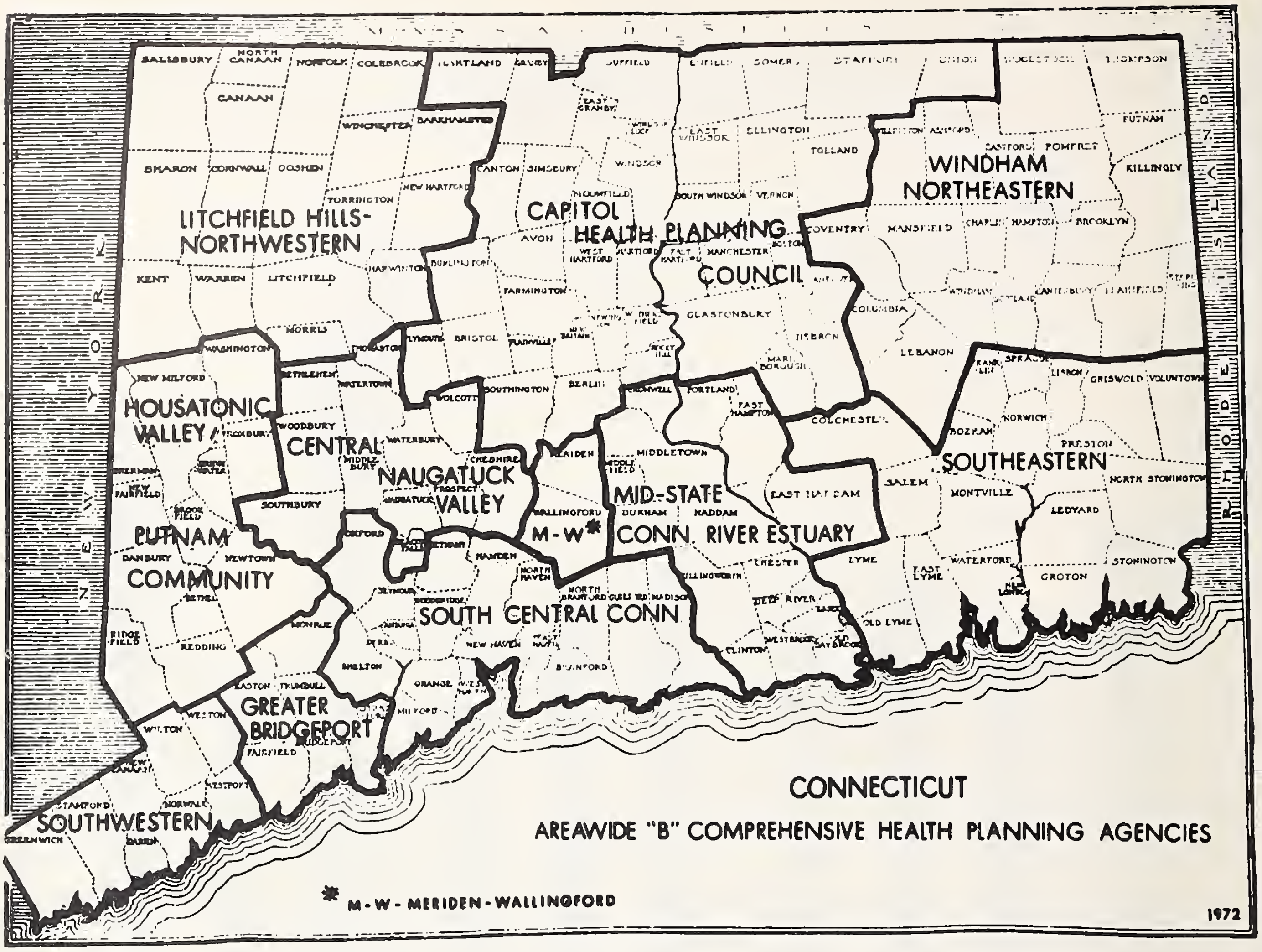
DISTRIBUTION OF PHYSICIANS IN CONNECTICUT
BY COMPREHENSIVE HEALTH PLANNING AREA
1971 AND 1973 PHYSICIAN PER 1,000 POPULATION RATIOS



population remains above the national average of about 1.57 per 1,000.[3] Within the state, however, geographic maldistribution as was indicated in 1971 data is again indicated in 1973 data. Physician concentration in highly urbanized areas such as the South Central, Capitol, and Southwestern areas resulted in respective rankings of 1, 2, and 3 in terms of physician per population ratios both in 1971 and in 1973. The relatively more rural Central Naugatuck, Southeastern, and Windham Northeastern areas maintained the lowest physician per population ratios in both data years. The magnitude of ratio differences between the high and low ratio areas also was found to be considerable in 1971 and 1973 data with a discrepancy of greater than .5 physicians per 1,000 population between areas ranked 3 and 9 and a larger discrepancy between areas with more extreme rankings. The South Central and Windham Northeastern area, for example, differed by approximately 1.5 physicians per 1,000 population.

Conclusion

The physician distribution situation in Connecticut apparently is reflective of the national situation with physicians overly concentrating in urban areas with resultant geographic maldistribution of physicians in relation to population. Fortunately Connecticut does appear to have a relatively high overall physician per population ratio and while large differences exist between comprehensive health planning areas even the areas with relatively low ratios are above shortage criteria as a whole. The major problem in Connecticut appears to lie in recruiting physicians for service in the indicated town clusters which currently have very few or no phy-



sicians. Another problem not addressed by the data presented in this study which is of greatest importance is the distribution and availability of physicians by specialty. While distribution of physicians as a whole may be useful indicators of the availability of physicians to population, more specific information on availability of specialty physicians in direct patient care is essential to understanding the current situation in a meaningful manner which can be transformed into effective planning. Adequate distribution of primary care physicians in Connecticut, in particular, is recognized to be extremely important and is currently being studied in great detail by the staff of the Commission on Hospitals and Health Care in conjunction with a Primary Care Task Force of recognized experts from various parts of the state. A report is expected in early 1975 which is intended to not only describe the current primary care situation but to also provide recommendations for short and long range improvements in availability and delivery of primary medical care.

REFERENCES

1. Hirakis, Sarah S. and Armondino, Norman L. "Distribution of Physicians in Connecticut." *Connecticut Health Bulletin,* 86:5, May, 1972, 135-144.
2. Hirakis, Sarah S. and Armondino, Norman L. "Distribution of Physicians Within Connecticut Comprehensive Health Planning Areas." *Connecticut Health Bulletin,* 86:6, June, 1972, 182-192.
3. American Medical Association, Center for Health Services Research and Development. *'73 Socioeconomic Issues of Health,* 1973, 40-41 (Inactive physicians subtracted from December 31, 1972 estimated total to derive national ratio comparable to state ratio.)

SUMMARY OF PROCEEDINGS
HOUSE OF DELEGATES—SEMI-ANNUAL MEETING
Storrs, Connecticut—November 20, 1974

Reports

Following welcoming remarks by William A. Whalen, Jr., WCMA President, on behalf of the host organizations—the Windham and Tolland County Medical Associations, the House of Delegates received reports or addresses from the following: The President (for the Officers), the Council, the COMPAC Board of Directors and the Connecticut Medical Institute. The reports of the President and of the Connecticut Medical Institute are published at the conclusion of this summary.

Luncheon Speaker

Members and guests of the House of Delegates were privileged to be addressed, following luncheon, by Dr. Tom E. Nesbitt, Nashville, Tenn., speaker of the AMA House of Delegates. Dr. Nesbitt's remarks covered the current financial situation of the AMA, the steps (including a proposed dues increase) that have been and will be taken by the AMA Board of Trustees to improve the situation, and the value and desirability of holding "unified membership" in organized medicine; i.e., at county, state and national levels.

Principal Actions Taken

Continuing the procedure established several years ago, all items of business coming before the House for consideration were referred to, heard by and reported on by Reference Committees. Actions taken on the reports of the three Reference Committees were as follows:

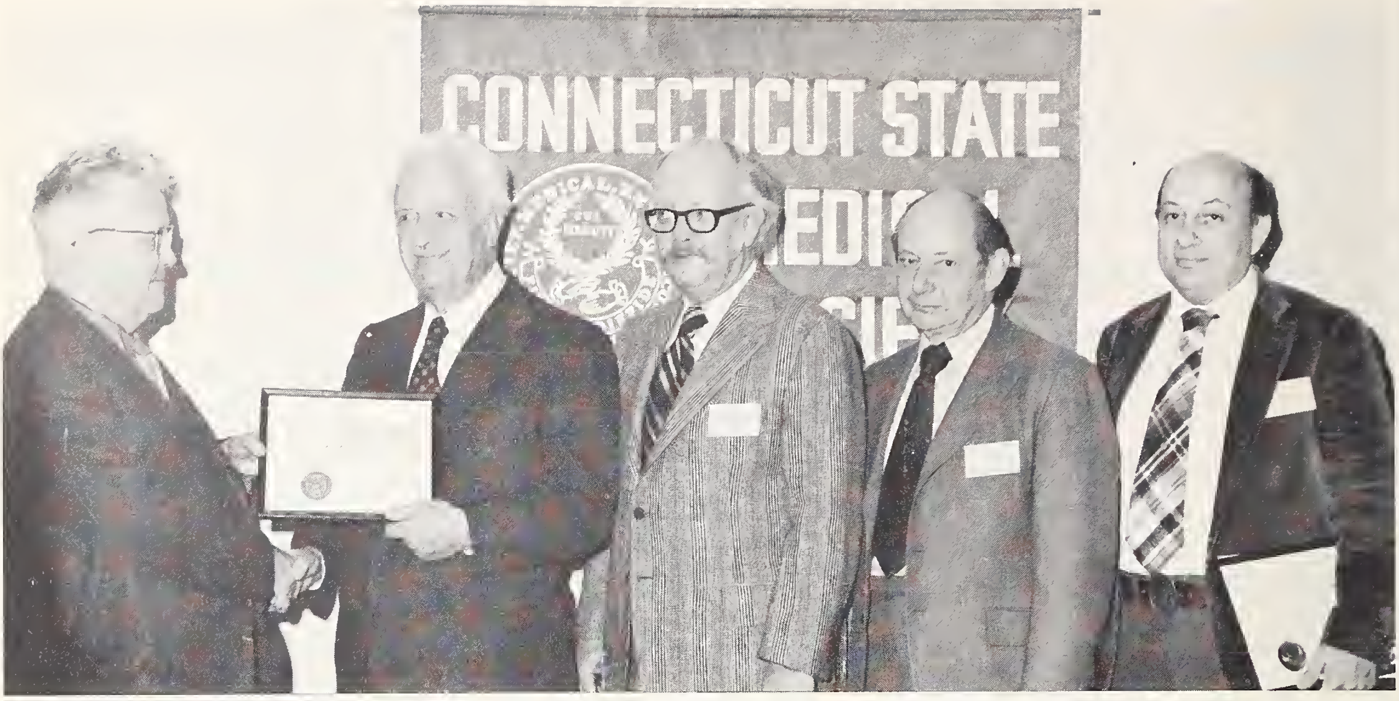
Reports of Reference Committee No. 1

(a) **Bylaws Amendments re Judicial Committee Procedures:** On this item, which had lain on the table since the 1974 annual meeting, the House of Delegates voted to approve the recommendation of the Reference Committee that the amendments be adopted as presented by the Council (which appeared in the November, 1974 issue of "Connecticut Medicine") with but a single change. The purpose of the change was to reemphasize the meaning of a "fair hearing" with respect to the Judicial Committee's evaluation of the procedures followed by a component County Association in hearing a complaint against a member.

(b) **Policy Statement on Acupuncture:** It was voted to approve the recommendation of the Reference Committee that the subject statement, as presented by the Council, be amended and adopted as follows: "Acupuncture is not at present a generally accepted method of medical practice, nor has it been shown scientifically to be an efficacious medical procedure. Acupuncture, therefore, should be performed only in investigative studies being carried out in an accredited medical center and/or an affiliated facility under the auspices of a formal committee on human research. In Connecticut, all acupuncture procedures should be performed by a licensed physician."

(c) **Resolution re Proposed AMA Policies:** On a two-part resolution introduced by the Board of Governors of NHCMA, the delegates (as recommended by the Reference Committee) voted "no" on the first part which advocated that the AMA continue to accept selected advertising for its several publications. As to the second part of the resolution, concerning modification of a proposed increase in AMA dues, a recommendation for adoption made by the Reference Committee was lost.

(d) **Delay in Medicaid Payments:** Having previously received a report from Leo P. Giardi, Hartford, chairman of the Liaison Committee with the State Welfare Department, concerning discussions with Welfare Department personnel re delays in Medicaid payments to all providers of health care services, the delegates voted to adopt a subject statement recommended by the Reference Committee as follows: "In view of current excessive delay in payments under Medicaid and, possibly, under similar tax-funded medical assistance programs, the House of Delegates of the Connecticut State Medical Society recommends that the State of Connecticut, through the Department of Welfare, make prompt compensation for all types of health care services rendered by providers in order to assure the continued viability of the medical assistance programs under the jurisdiction of the Department of Welfare. The House of Delegates reaffirms its belief that members of the Connecticut State Medical Society should continue to accept responsibility for rendering medical care to welfare beneficiaries."



Dr. James H. Root, Jr., left, President of the Connecticut State Medical Society, presented past service awards to four physicians during the recent Semi-Annual meeting of CSMS held at the University of Connecticut.

Receiving citations in recognition of their service as Associate Councilor and as Councilor were Dr. Kurt S. Pelz of Clinton and Dr. Carl W. Johnson of Thompsonville. Recipient of an inscribed Silver Revere Bowl for his service as Treasurer of CSMS was Dr. Hilliard Spitz of New London and receiving a citation as Associate Councilor was Dr. Saul S. Milles of New Haven.

Not pictured but honored as an Associate Councilor and Councilor was Dr. Bernard O. Nemoitin of Stamford.

Reports of Reference Committee No. 2

(a) **CSMS-Aetna Professional Liability Program:** It was voted to approve a recommendation of the Reference Committee that the following subject resolution be adopted:

RESOLVED: That the House of Delegates of the Connecticut State Medical Society initiate the investigation of alternate approaches to the management of professional liability, such investigation to include but not be limited to a study of the feasibility of no-fault professional liability insurance and/or the creation of a compulsory statewide arbitration panel; and be it further

RESOLVED: That the House of Delegates direct the Committee on Professional Liability to undertake the aforesaid investigation and study and report its findings to the next meeting of the House.

(b) **Unified Membership in Organized Medicine:** It was voted to approve a recommendation of the Reference Committee that a subject resolution be adopted as follows:

RESOLVED: That the House of Delegates of the Connecticut State Medical Society urge that the Society and the component County Medical Associations promote vigorously a policy of unified membership in the County Association, the State Society and the AMA.

Report of Reference Committee No. 3

1975 Budget: The hearing conducted by Reference Committee No. 3 was devoted exclusively to the budget for 1975, as prepared by the Council's Fiscal Subcommittee and approved by the Council. The Treasurer, Carl W. Johnson, and other members of the Fiscal Subcommittee responded to several questions raised from the floor. The House voted to approve the recommendations of the Reference Committee as follows: (a) That the budget for 1975, as presented by the Council, be approved; (b) that an assessment of $10 be levied on each dues-paying member in 1975 to cover the costs (approximately $25,000) of establishing the Connecticut Medical Institute, Inc., during 1974 (as voted by the House on 3/14/74): and (c) that the dues for 1975 be set at $85 per dues-paying member.

REPORT OF THE PRESIDENT

James H. Root, Jr., Waterbury

At the last meeting of the Society in May, 1974, several areas of endeavor were identified including Education for Health, Minimum Standards Health Insurance Guidelines, Continuing Medical Education, the Connecticut Ambulatory Care Study PSROs and the Connecticut Medical Institute (CMI). I think we have made good progress so far in all of these areas.

I. In Health Education we have mounted quite an effort. This can be divided into three parts: 1.) surveying the health education needs in 169 towns and municipalities in Connecticut; 2.) implementing these needs through the school system by putting health education courses in the schools; and 3.) implementing health education for adults through other agencies such as hospitals, health agencies, chambers of commerce, rotary clubs, etc. Our Statewide Planning Committee in its study of Deficiencies in Medical Care in Connecticut concluded that Education for Health was one of the deficiencies. Our Woman's Auxiliary agreed to take this on as one of their main projects both in the area of survey and implementation.

Health education in schools is being promoted in two ways:

1.) through the Legislature and State Department of Education and

2.) at the local level through local Boards of Education and school superintendents. On November 12th I testified before the Joint Committee on Education of the State Legislature.

One of our long range objectives is to get introduced into the curriculum of schools courses on education for health, kindergarten through senior year high school.

We put a lot of effort into making high quality medical care available to all people but spend little time, by comparison, in seeing to it that people are knowledgeable enough to recognize early the approach of ill health, both somatic and psychological.

Ten other recommendations of the Statewide Planning Committee on the Deficiencies of Health Care in Connecticut have been assigned to various committees of the CSMS to implement the correction thereof.

II. The second area of effort was the development of guidelines for minimum standards health insurance contracts. The Third Party Payment Committee has been working on this for some time. The plan to implement this is to first publish a booklet telling people for what they should be covered in health insurance packages. The second step is to put the seal of approval of the CSMS on those packages of health insurance coverage that meet those standards. The booklet is almost completed and will be sent to the Council for approval within the next few months.

III. The third area of endeavor is in the area of Continuing Medical Education. The medical profession is finding that it is more and more accountable to the public at large and to the federal government. No longer can the attitude prevail that "it is right because I did it." We are being reviewed by our peers, and we must show evidence of continuing medical education. Relicensure is not only inevitable but imminent. The question is how should relicensure take place? It can be accomplished by re-examination or it can be accomplished via the route of continuing medical education credits. This latter route would be much more acceptable to most of us. If we go in this direction before the government makes up its mind to impose something upon us, we have more chance of calling the shots.

The American Academy of Family Practice already has taken the way of credits for continuing medical education. Certain local hospitals require the same for staff reappointments.

In my mind the question of compulsory credit accumulation should be re-examined by this House. I believe that our Committee on Continuing Medical Education has a resolution to this end on the floor of the House today. I don't find it—at least it was planning to do so when I met with them last. Since we rejected this idea a few years ago, the Committee has been trying to accomplish this end through local hospital staffs and governing bodies.

Now I know full well what the word "compulsion" does to many of you. It turns you off and it antagonizes you. And this I hate to do. But if we stubbornly try to pretend that this social evolution or revolution is not here, we shall simply drown in it. No one knows better than I how sick you are of people telling you what you must and must not do, even if it is one of your own.

IV. The fourth endeavor has been to wind up successfully the Connecticut Ambulatory Care Study. This study should be completed by April of 1975. There have been financial difficulties due to cutbacks in national grants.

The study has been limited to the study of practice patterns of private physicians and hospital out-patient departments, since neither the Falk HMO nor the Yale Health Plan would participate. We got 100% cooperation from the hospitals and enough private physicians to make the study valid.

The study has been limited as to quality because the cost factors had to be dropped for lack of funds.

Those of us who are on the scene in this effort feel that enough data will have been collected and analyzed to make the study very worthwhile.

V. and VI. The implementation of the PSRO law and the birth of the Connecticut Medical Institute are very much interrelated and can be discussed as one topic. Dr. James Kenney will be giving us today an updated report on the structure and activities of the CMI. We must remind ourselves that the long-range goal of the CMI is to organize statewide peer review systems and that the immediate short term goal is to aid and help coordinate the four PSRO areas in their birth and development.

Therefore, at the moment, the CMI is acting as a technical support center for the four PSROs. Both the CMI and the four PSROs successfully obtained their planning grants from HEW with the aid of American Health Systems. The CMI and the four PSRO areas already have hired their executive staffs and are keeping up to their time tables of development.

As a matter of fact the CMI has been praised by HEW for breaking virgin ground and setting a good example for other technical support centers in the nation. As you know, all dues-paying members of the Society will be assessed $10 to pay the American Health Systems "obstetrician" for delivering this CMI "baby" and, as parents, you can be proud of what your offspring is accomplishing.

Other matters:

There are a few other things which should be mentioned briefly in which we have been interested in the last six months.

It seems evident, particularly after the Democratic landslide earlier this month, that a National Health Insurance bill will be upon us within one or two years. I hope that the fact that we are participating in the PSRO implementation will cause Congress to allow more of our input into this NHI bill and that they will give us a more prominent role in implementing whatever bill does come out—that is if we can implement it at all and still preserve the things that are sacred to us as a medical profession.

We have worked hard on a statement concerning Acupuncture. It is our feeling that this should be done only by physicians and possibly dentists and that it should be done only as a research project in affiliation with a medical teaching institution or research center.

The matter of unified membership has been discussed and even may be brought up today. Unified membership means that every member of a county medical association in Connecticut would have to be a member of the state society and the AMA. This is being given a great deal of study and, in my opinion, should be one of our ultimate goals. But there I go with the word "compulsion" again. I wonder what we can do to get around it. The AMA really does a lot for us, you know. The AMA does more for the medical profession. In the November issue of *Connecticut Medicine* the matter is discussed in some depth. But I shall not say any more about this matter at this time. It will be gone into more at a later date.

Trem Bradley has done a great job with his Cancer Coordinating Committee. I could go on and on with examples like this. Chick Cramer is doing a good job on the Hospital Cost Commission. Fred Fabro has made great improvements in the Journal. Andy Canzonetti has been made a member of the PSRO Board. Fred Weber and Dave Grendon have done excellent jobs with the Statewide Planning Committee and the CACS.

But one has to stop somewhere. Thank you very much.

Report on Connecticut Medical Institute

James D. Kenney, M.D.,
President and Treasurer, CMI, Inc. .

1. Within the past year the Connecticut Medical Institute has been incorporated and has been funded by a grant from the Department of Health, Education and Welfare as a "support center" within the framework of the legislation which enabled the founding of PSRO's.
2. The board composition of the Connecticut Medical Institute is as follows: President and Treasurer, James D. Kenney, M.D., Connecticut State Medical Society; Vice-President, James H. Root, Jr., M.D., Connecticut State Medical Society; Secretary, Mr. John Ives, Connecticut Hospital Association; Andrew J. Canzonetti, M.D., Hartford County PSRO, Inc., Foundations for Medical Care in Connecticut; Allyn B. Dambeck, M.D., Eastern Connecticut PSRO, Inc.; Rector I. Davol, M.D., PSRO of Fairfield County, Inc.; Vincent A. DeLuca, Jr., M.D., Chairman of the Committee on Continuing Medical Education; Mr. Joseph Fontana, Connecticut Health Insurance Council; Jerome K. Freedman, M.D., Connecticut Area II PSRO, Inc.; David A. Grendon, M.D., Connecticut Area II PSRO, Inc.; Orvan W. Hess, M.D., Connecticut State Medical Society; Edward A. Kamens, M.D., Connecticut State Medical Society; John F. Kelly, M.D., Eastern Connecticut PSRO, Inc.; Stewart A. King, M.D., PSRO of Fairfield County, Inc.; Douglas S. Lloyd, M.D., Commissioner of Health; Herbert M. Magram, M.D., Connecticut State Medical Society; Mr. James F. Morrison, Department of Welfare; Lawrence K. Pickett, M.D., Connecticut Hospital Association; Mr. David Sheehan, Blue Cross of Connecticut; R. Bruce Thayer, M.D., Connecticut Medical Service, Inc.; David L. Warren, M.D., Hartford County PSRO, Inc., Hartford County Health Care Foundation; Mr. Howard V. Wry, Connecticut Commission on Hospitals and Health Care.
3. The Institute is headquartered at 90 Sargent Drive, New Haven, Connecticut.
4. The Institute's staff at the moment consists of an Executive Director, Mr. Joseph Marin, three other staff in executive positions. In addition there are two secretaries.
5. Progress:

(a) A formal plan for informing physicians and others in health related matters about PSRO's, has been constructed and approved for implementation by HEW. Its enactment is now underway.

(b) Aid to the four PSRO's in developing plans for "conditional status" has also been provided. In this regard CMI has done the job which the PSRO's would have had to hire consultant firms to accomplish. Success has been favored by a good staff and a successful interaction—in various ways precedent setting—with HEW counterparts. All four PSRO's are now equipped with documents and plans necessary for progress to "conditional status." Newly acquired staff will help to put these into action.

(c) A comprehensive catalogue of specialty and sub-specialty expertise available both statewide and within PSRO's areas is now under development.

6. Philosophy: This remains one of service. Executive action, professional judgements, and control of conduct of events remain the province of the PSRO's. CMI will be strong only as it succeeds in service.

Awards for CSMS Service

The President, James H. Root, Jr., presented awards for past service to the Society to the following:

Officers

Hilliard Spitz, New London .... Treasurer 1971-1974

County Councilors

Fairfield

Bernard O. Nemoitin, Stamford
.... Councilor 1972-1974
.... Associate Councilor 1968-1972

Hartford

Carl W. Johnson, Thompsonville
.... Councilor 1971-1974
.... Associate Councilor 1967-1971

New Haven

Kurt S. Pelz, Clinton .... Councilor 1970-1974
.... Associate Councilor 1966-1970

Saul S. Milles, New Haven
.... Associate Councilor 1972-1974

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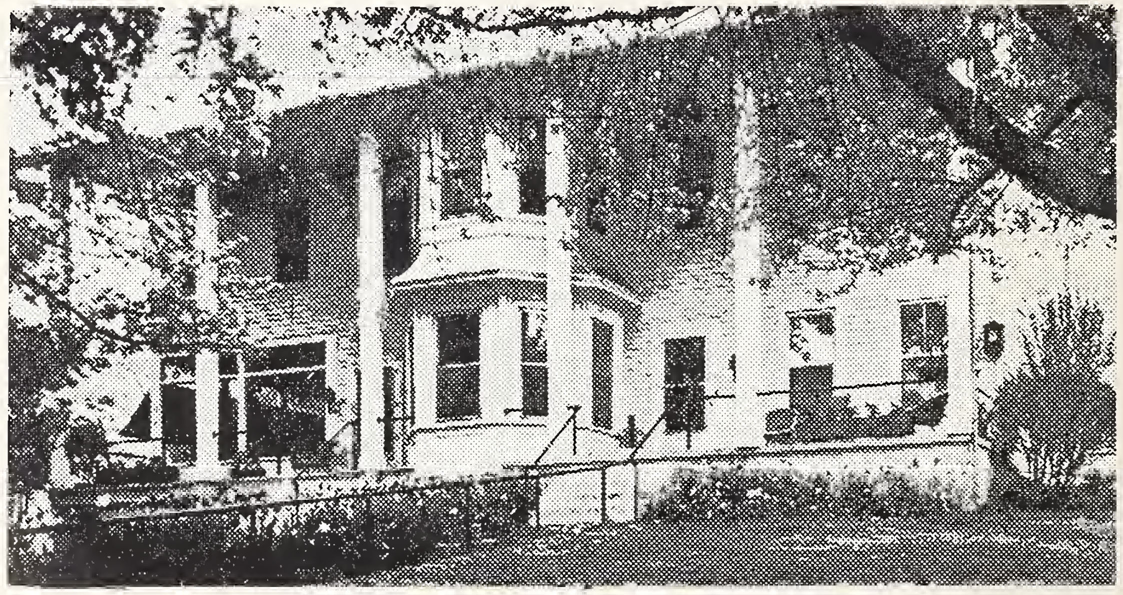

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Josephine M. Fiala, Owner

Is He a Source of Information?

Yes, with certain reservations. The average sales representative has a great fund of information about the drug products he is responsible for. He is usually able to answer most questions fully and intelligently. He can also supply reprints of articles that contain a great deal of information. Here, too, I exercise some caution. I usually accept most of the statements and opinions that I find in the papers and studies which come from the larger teaching facilities. It goes without saying that a physician should also rely on other sources for his information on pharmacology.

Training of Sales Representatives

Ideally, a candidate for the position as a sales representative of a pharmaceutical company should be a graduate pharmacist who has a questioning mind. I don't think this is possible in every case, and so it becomes the responsibility of the pharmaceutical company to train these individuals comprehensively. It is of very great importance that the detail man's knowledge of the product he represents be constantly reviewed as well as updated. This phase of the sales representative's education should be a major responsibility of the medical department of the pharmaceutical company.

I am certain that most of these companies take special care to give their detail men a great deal of information about the products they produce — information about indications, contraindications, side effects and precautions. Yet, although most of the detail men are well informed, some, unfortunately, are not. It might be helpful if sales representatives were reassessed every few years to determine whether or not they are able to fulfill their important function. Incidentally, I feel the same way about periodic assessments of everyone in the health care field, whether they be general practitioners, surgeons or salesmen.

Value of Sampling

I personally am in favor of limited sampling. I do not use sampling in order to perform clinical testing of a drug. I feel that drug testing should rightly be left to the pharmacology researcher and to the large teaching institutions where such testing can be done in a controlled environment.

I do not use samples as a "starter dose" for my patients. I do, however, find samples of drugs to be of value in that they permit me to see what the particular medication looks like. I get to see the various forms of the particular medication at first hand, and if it is in a liquid form I take the time to taste it. In that way I am able to give my patients more complete information about the particular medications that I prescribe for them.

---

capacity they are indeed useful; particularly in the fact that they disseminate broadly based educational material and serve not just as "pushers" of their drugs.

The Other Side of the Coin

Obviously, the pharmaceutical companies are not producing all this material as a labor of love — they are in the business of selling products for profit. In this regard the ambitious and improperly motivated sales representative can exert a negative influence on the practicing physician, both by presenting a one-sided picture of his product, and by encouraging the practitioner to depend too heavily on drugs for his total therapy. In these ways, the salesman has often distorted objective reality and undermined his potential role as an educator.

The Industry Responsibility

Since the detail man must be an information resource as well as a representative of his particular pharmaceutical company, he should be carefully selected and thoroughly trained. That training, perforce, must be an ongoing one. There must be a continuing battle within and with the pharmaceutical industry for high quality not only in the selection and training of its sales representatives, but also in the development of all of its promotional and educational material.

The industry must be ready to accept constructive as well as corrective criticism from experts in the field and consumer spokesmen, and be willing to accept independent peer review. The better educated and prepared the salesman is, the more medically accurate his materials, the better off the pharmaceutical industry, health professionals and the public—*i.e.,* the patients—will be.

Physician Responsibility

The practicing physician is in constant need of up-dated information on therapeutics, including drugs. He should and does make use of drug information and answers to specific questions supplied by the pharmaceutical representative. However, that information must not be his main source of continuing education. The practitioner must keep up with what is current by making use of scientific journals, refresher courses, and information received at scientific meetings.

The practicing physician not only has the right, but has the responsibility to demand that the pharmaceutical company and its representatives supply a high level of valid and useful information. I feel certain that if such a high level is demanded by the physician as well as the public, this demand will be met by an alert and concerned pharmaceutical industry.

From my experience, my impression is that sectors of the pharmaceutical industry are indeed ethical. I challenge the industry as a whole to live up to that word in its finest sense.

*Pharmaceutical
Manufacturers Association
1155 Fifteenth Street, N.W.
Washington, D.C. 20005*

P·M·A

FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, Conn. 06511
Telephone 865-0587

Francis G. Sweeney
Assistant Executive Director
Public Affairs

William R. Richards, M.D.
Executive Director
Josephine P. Lindquist
Associate Executive Director

Leonard R. Tomat
Assistant Executive Director
Scientific Activities

Summary of Actions
Council Meeting
Wednesday, November 6, 1974

I. Attendance

Present in addition to the Chairman, Dr. D. A. Grendon, and the Vice Chairman, Dr. C. W. Johnson, were: Drs. Root, Jr., VanSyckle, Backhus, Brandon, Nolan, Fabro, Bradley, Hess, Granoff, Hecklau, Rubinow, Ragland, Jr., James, Freedman, Roch, Harkins and Sonnen.

Also present were: Mrs. Lindquist, Mr. Tomat, Mr. Sweeney and Dr. Richards.

Absent were: Drs. Spitz, Gardner, Cramer, Krinsky, Dambeck, Kamens, McGarry, Canzonetti, Sadowski, Magram, Mendillo, Eslami, Barrett and Klare.

II. Routine Business

Approval of Minutes

As published and distributed, it was VOTED to approve the minutes of the meeting of October 24, 1974.

Life Memberships

It was VOTED to approve applications for Life Membership received from the following eligible Active Members:

Louis C. Backhus, 58 Central Avenue, Waterbury
Edwin H. Basden, 828 Main Street, Willimantic
Frank E. Smith, Jr., Salisbury
Frederick F. Smith, 1 Dixwell Plaza, New Haven

Date of Next Meeting

The Chairman scheduled the next meeting of the Council for Thursday, December 19, 1974.

III. Old, New and Special Business

Election of Student Members

It was VOTED to elect to CSMS Student Membership thirty-four Connecticut residents who are enrolled in American medical schools. The names of those elected will be published in an early issue of the Journal.

Resignations, Appointments, Etc.

(a) *Committee on Public Health:* It was VOTED to accept the resignation of Joseph M. Wool, New London, and to thank Dr. Wool for his past service to the Society.

(b) *Judicial Committee:* It was VOTED to accept, with regret, notice of the resignation of David S. Hastings, Stafford Springs, as a Tolland County Association representative of the Judicial Committee, and it was further VOTED to appoint James R. Cullen, Somers, to replace Dr. Hastings as a member of the Committee for the balance of the term 1971-75.

Reports—Fiscal Subcommittee

(a) *Journal Survey Questionnaire:* A recommendation of the F.S. that $750 be allocated to the Journal budget with which to carry out a readership survey for the Journal, as proposed by the Editorial Committee, failed of approval. It was then VOTED to urge the Editorial Committee to give favorable consideration to sending the questionnaire to the membership via a "tearout page" published in the Journal, with return postage guaranteed, and to approve the expenditure of sufficient funds to implement the proposed survey in this manner. All charges for the project are to be made to the Journal budget.

(b) *3rd AMA Leadership Conference, Chicago, 1/24-26/75:* It was VOTED to authorize the attendance of James H. Root, Jr., Waterbury, at this Conference and to reimburse him for usual expenses in the amount of approximately $450.

Report of Fiscal Subcommittee—1975 Budget

It was VOTED to accept for filing a report of the Fiscal Subcommittee concerning the Society's budget for 1975, consisting of an accounting of the financial experience for the first 9 months of 1974 and a budget for 1975 as proposed by the Subcommittee. With minor amendment, the Council VOTED to approve the 1975 budget, as prepared by the Subcommittee; to approve the Subcommittee's recommendation that the membership dues for 1975 be set at $85.00 and that each dues-paying member be assessed $10.00 to cover the costs associated with the establishment of the Connecticut Medical Institute, Inc.; and that the budget and the recommendations be transmitted to the House of Delegates on 11/20/74 with the Council's recommendation for approval.

It was further VOTED to approve a recommendation that, as a matter of fiscal policy, committees of the Society be authorized to determine for themselves the place, time and menu of their dinner meetings, with the understanding that expenditures for food in excess of the budget allocations for food, based on meals served at the Society's headquarters building, will be borne individually by the members of the committees participating.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on November 6, 1974. Detailed minutes of the meeting are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

Thirty-four student members were elected to the society.

STUDENT MEMBERS

Thomas P. Anderson, 43 Caya Ave., West Hartford, Conn.
University of Connecticut—Class of 1978
Pre-Med: Bucknell
Parent: Gorooj Arthur

Peter Basch, 40 Grenhart St., West Hartford, Conn.
George Washington Univ.—Class of 1978
Pre-Med: Trinity College
Parent: William R. Basch

Joahn N. Bodurtha, 56 Hayes Lane, Ridgefield, Conn.
Yale University—Class of 1978
Pre-Med: Swarthmore College
Parent: James Bodurtha

Scott E. Brodie, 37 Burr Farms Rd., Westport, Conn.
Cornell University—Class of 1978
Pre-Med: Wesleyan University
Parent: Richard E. Brodie

John M. F. Conte, 1R Talcott Forest Rd., Farmington, Conn.
University of Connecticut—Class of 1978
Pre-Med: Trinity College
Parent: Harold S. Conte

Leonard A. Copertino, 59 Brookside Dr., Trumbull, Conn.
University of Connecticut—Class of 1978
Pre-Med: Fairfield Univ.
Parent: Leonard F. Copertino

Richard Debowsky, 44 Brittany Farms Rd., New Britain, Conn.
University of Connecticut—Class of 1978
Pre-Med: Univ. of Conn.
Parent: Henry Debowsky

Stuart B. Dubin, 1355 Ridge Rd., North Haven, Conn.
Yale University—Class of 1978
Pre-Med: Yale College
Parent: Samuel Dubin

Eric B. Einstein, 189 Turner Rd., Stamford, Conn.
Yale University—Class of 1978
Pre-Med: Brown University
Parent: Robert Einstein

Paul B. Fischer, Waterman Rd., Lebanon, Conn.
University of Connecticut—Class of 1978
Pre-Med: Erlham College
Parent: Elmer M. Fischer

Linda J. Gardiner, 393 Mansfield St., New Haven, Conn.
Yale University—Class of 1978
Pre-Med: Fordham, Yale
Parent: Richard E. Lucey

Arthur L. Gendron, Jr., 6 Harrison St., Windsor Locks, Conn.
Boston University—Class of 1978
Pre-Med: Boston Univ.
Parent: Arthur Gendron, Sr.

George M. Golenwsky, 40 Melrose St., Bristol, Conn.
Yale University—Class of 1978
Pre-Med: Cornell Univ.
Parent: Mario L. Golenwsky

Mark G. Graham, 280 Stratford Road, Stratford, Conn.
University of Connecticut—Class of 1978
Pre-Med: Fairfield Univ.
Parent: Albert C. Graham

Lloyd S. Gray, Jr., 183 Hartford Road, Apt. 6B,
New Britain, Conn. 06053
University of Connecticut—Class of 1978
Pre-Med: Wichita State Univ.
Parent: Lloyd S. Gray

Robert Hershfield, 403 Derby Avenue, Orange, Conn.
Yale University—Class of 1978
Pre-Med: Brown University
Parent: David H. Hershfield

Paul Joseph Hesketh, 172 Allen Street, Apt. 8,
New Britain, Conn. 06053
University of Connecticut—Class of 1978
Pre-Med: Boston College
Parent: William Hesketh, Jr.

Virginia Howell, 5 Cheryl Court, Cromwell, Conn.
University of Connecticut—Class of 1978
Pre-Med: Oberlin College
Parent: C. Cortland Howell

Diana Louise Jeannotte, 28 Upper Bartlett Rd.,
Quaker Hill, Conn.
Boston University—Class of 1978
Pre-Med: Boston University
Parent: Joseph Ernest Jeannotte

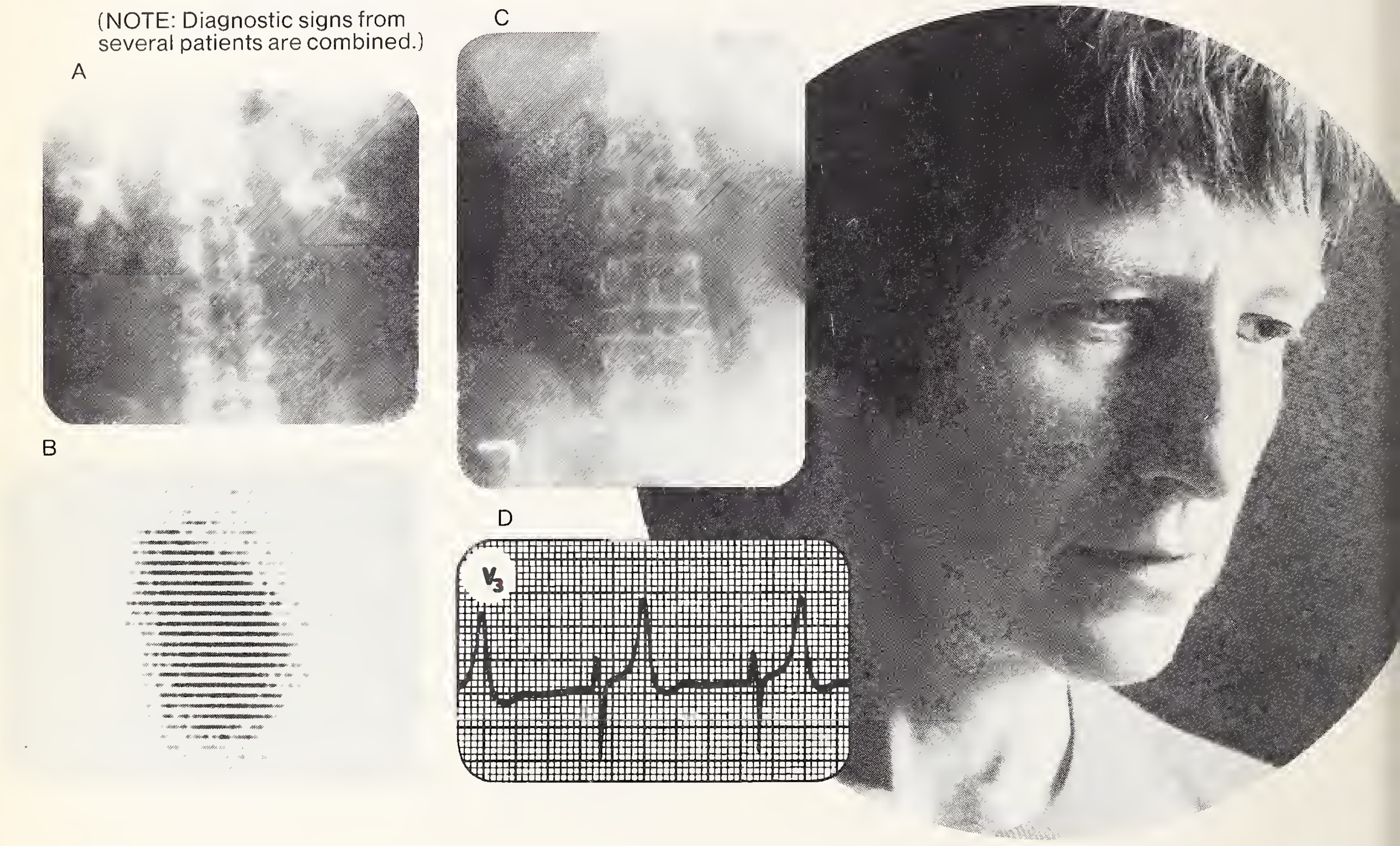
Robert Scott Jones, 26 Highbrook Road, Norwalk, Conn.
University of Connecticut—Class of 1978
Pre-Med: New York Univ.
Parent: Martling B. Jones

Donald Alan Kennerly, 42 Holly Lane, Darien, Conn. 06820
Washington University—Class of 1980
Pre-Med: Harvard College
Parent: G. Warren Kennerly

Continued on Page 63

What's wrong with this "patient"?*

(NOTE: Diagnostic signs from several patients are combined.)



Supplementary vitamins in febrile illness

Poor appetite. Depletion of vitamin C. Possible antibiotic interference with intestinal microorganisms that synthesize the B-complex vitamins. These factors may lead to a vitamin deficient state in the patient with advanced chronic infection or severe acute febrile illness.

During the recovery period, high potency Berocca Tablets can supplement inadequate dietary supply of both B-complex and C vitamins and can help meet essential vitamin requirements in the patient with these types of infection.

When nutritional supplementation is indicated in infection

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With balanced, high potency
vitamin B-complex and 500 mg vitamin C
Virtually no odor or aftertaste
Low priced Rx formula

**Diagnosis appears on next page.*

See next page for summary of Product Information.

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Sig: 1 Tab
B.I.D.

DIAGNOSIS: Chronic pyelonephritis is revealed in these illustrations: (A) Intravenous pyelogram showing irregular renal outline and deformed pelvis; (B) Renal scan showing decreased renal size; (C) X-ray of the lumbar spine and pelvis showing osteoporosis; (D) V3 lead showing T-wave elevation due to hyperkalemia.

Please see complete product information, a summary of which follows:

Each Berocca Tablet contains:

Thiamine mononitrate ($Vitamin B_1$)	15 mg
Riboflavin (Vitamin B_2)	15 mg
Pyridoxine HCl (Vitamin B_6)	5 mg
Niacinamide	100 mg
Calcium pantothenate	20 mg
Cyanocobalamin (Vitamin B_{12})	5 mcg
Folic acid	0.5 mg
Ascorbic acid (Vitamin C)	500 mg

Indications: Nutritional supplementation in conditions in which water-soluble vitamins are required prophylactically or therapeutically.

Warning: Not intended for treatment of pernicious anemia or other primary or secondary anemias. Neurologic involvement may develop or progress, despite temporary remission of anemia, in patients with pernicious anemia who receive more than 0.1 mg of folic acid per day and who are inadequately treated with vitamin B_{12}.

Dosage: 1 or 2 tablets daily, as indicated by clinical need.

Available: In bottles of 100.

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Donald Stuart Levine, 61 Tumblebrook Road,
Woodbridge, Conn. 06525
University of Connecticut—Class of 1978
Pre-Med: Univ. of Penn.
Parent: Manfred Levine

Mark Allen Mahoney, 37 Fairview St., New Britain, Conn.
University of Connecticut—Class of 1978
Pre-Med: Worcester Polytechnic Institute
Parent: Paul C. Mahoney

Michael R. Mastrangelo, 19 Grandview Avenue,
Stamford, Conn.
University of Kentucky—Class of 1978
Pre-Med: University of Kentucky
Parent: Angelo Mastrangelo, Jr., M.D.

James Lewis Moore, 26 Sunset Terrace, West Hartford, Conn.
New York University of Medicine—Class of 1978
Pre-Med: Duke Univ.
Parent: James Joseph Moore

Keith L. Mullenger, 44 Ryders Lane, Wilton, Conn.
Washington University—Class of 1978
Pre-Med: Iowa State University
Parent: Keith E. Mullenger

James Stevan Nagel, 152 Juniper Dr., Avon, Conn. 06001
University of Connecticut—Class of 1978
Pre-Med: Mass. Institute of Technology
Parent: James Carleton Nagel

Edward Arnold Nelson, Spooner Hill Road, South Kent, Conn.
University of Rochester—Class of 1978
Pre-Med: Alleghany College
Parent: George A. Nelson

Rocco Orlando, III, Knollwood Road, Bethany, Conn. 06525
University of Connecticut—Class of 1978
Pre-Med: Hamilton College
Parent: Rocco Orlando

Brian Kevin Phelan, 205 Stanwood Drive, New Britain, Conn.
University of Connecticut—Class of 1978
Pre-Med: Johns Hopkins Univ.
Parent: Edward J. Phelan

Thomas Edward Quinn, 27 Greystone Road,
West Hartford, Conn.
Boston University—Class of 1978
Pre-Med: Amherst College
Parent: Charles Joseph Quinn

Ann Rosemond Skopek, 41 Village Hill Road,
Stafford Springs, Conn.
University of Connecticut—Class of 1978
Pre-Med: Smith College
Parent: Richard Skopek

Brad Allen Volpi, 3 Westridge Drive, Simsbury, Conn.
University of Connecticut—Class of 1978
Pre-Med: University of Calif.
Parent: Eugene Robert Volpi

David Lawrence Waltos, 177 Calhoun St., Torrington, Conn.
George Washington University—Class of 1978
Pre-Med: Trinity College
Parent: Samuel J. Waltos

OBITUARIES

Max R. Goldstein, M.D.
1917 - 1974

Dr. Max Richard Goldstein died suddenly in Hartford Hospital on October 19, 1974, after a short illness.

He was born in Provo, Utah and spent part of his childhood in the West before moving to Hartford. He was graduated from Weaver High School and Dartmouth College in 1939 and received his medical degree from Hahnemann Medical College in Philadelphia in 1943. Dr. Goldstein interned at Mt. Sinai Hospital, Baltimore, Maryland, and at New Britain General Hospital. Following internship, he served two years at the Lahey Clinic as a Fellow in medicine and began his practice in Hartford in internal medicine in 1946. He was on the staff at Mt. Sinai and Hartford Hospital.

He served in the Army as a major and was chief of medical service in Berlin, Germany, from 1955 to 1957. Dr. Goldstein was a dedicated and devoted physician, sensitive and sympathetic to the problems of his patients, and he served their needs unselfishly throughout his active medical career.

Dr. Goldstein was a member of the Hartford County Medical Society, the Connecticut State Medical Society and the American Medical Association. He served on the Board of Directors of the Hartford County Medical Society and was past president. He was a member and chairman of the Legislative Committee of the County and State Medical Societies and was actively interested in the emerging new health care programs and made several appearances on TV in order to inform the public in these new trends in medical care. He was also an honorary trustee of Haifa University.

Dr. Goldstein was one of the leading state amateur golfers and was former club champion at Tumblebrook Country Club.

He leaves his wife, Yvonne Berchner Goldstein, three sons, David, Robert, and Steven, a daughter, Mrs. Mary Marcus and a sister, Mrs. Enid Ancell.

SAMUEL H. COHN, M.D.

Otto G. Wiedman, M.D.
1884 - 1974

Dr. Otto G. Wiedman of Hartford, Connecticut, died at the Hartford Hospital July 25, 1974. Born in Philadelphia, Pennsylvania, he was graduated in 1905 from the School of Medicine of the University of Pennsylvania. He received residency training at the New York Neurological Institute and the Boston Psychopathic Hospital.

Before receiving his training in neurology and psychiatry, he did general practice in Hartford for a short period of time. He joined the staff of the Hartford Hospital in 1919 and had the distinction of becoming the elected president of its medical and surgical staff on two separate occasions, holding that position from 1939 to 1941 and again in 1944 to 1945. Dr. Wiedman also was honored by Newington Children's Hospital for more than fifty years of service on the active staff. He was fond of recounting some of his early experiences at that institution when he told how he gave drop ether anesthesia for surgery being performed on the kitchen table in the then young hospital.

He was former director of the Connecticut Society for Mental Hygiene and was appointed director of the Division of Mental Hygiene, Connecticut State Health Department in 1922. Dr. Wiedman was formerly consulting neurologist at New Britain General Hospital and Manchester Memorial Hospital and medical director of the Hartley-Salmon Clinic, Hartford. He was examining surgeon for the Newington Veterans Hospital.

Dr. Wiedman was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. A fellow of the American College of Physicians and a diplomat of the American Board of Psychiatry and Neurology and a fellow of the American Psychiatric Association. He was vice president of the New England Society for Psychiatry in 1935 and president of the Hartford Medical Society in 1937.

Dr. Wiedman was an avid reader, always remained abreast of the most recent literature, and was held in great esteem as a teacher by all those who came in contact with him. Even after he retired from active practice he continued to attend patients at Newington Children's Hospital regularly to the last few years of his life.

He is survived by his wife, Ann Silverman Wiedman, of Hartford.

Dr. Otto Wiedman will long be remembered for his outstanding professional accomplishments, his many contributions to the hospitals with which he was associated, and for the many kindnesses he extended to colleagues and patients in his quiet unostentatious manner.

BURR H. CURTIS, M.D.

In Memoriam

Audet, Charles H., Sr., University of Maryland, 1917. Before his retirement in 1957 Dr. Audet was a practicing surgeon in the New Haven area since 1917. He was a past president of the Waterbury Medical Association. Also, a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Audet died in Ft. Lauderdale, Florida, at the age of 79.

Hagedorn, Maxwell E., Jefferson Medical School, 1945. Dr. Hagedorn was a practicing orthopedic surgeon in the Hartford area since 1946. Since 1961 he had been senior attending orthopedic surgeon and chief of orthopedics at the New Britain General Hospital. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Hagedorn died November 9, 1974, at the age of 54.

Hastings, Louis P., University of Vermont, 1923. Dr. Hastings was a pathologist in the Hartford area since 1928. He was a pioneer in laboratory medicine and a retired director of the St. Francis Hospital laboratory department, a post he held for 36 years. He was a member of the Hartford County Medical Association, the New Haven County Medical Association and the American Medical Association. Dr. Hastings died October 19, 1974 at the age of 78.

Laakso, Andrew O., Cornell University, 1937. Dr. Laakso was a former chief of surgery at the Day Kimball Hospital in Putnam, and honorary vice counsel of Finland for the State of Connecticut. He was a member of the Windham County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Laakso died November 17, 1974 at the age of 63.

O'Brasky, George H., Jefferson Medical School, 1920. Before his retirement Dr. O'Brasky was a roentgenologist in the New Haven area since 1920. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. O'Brasky died November 13, 1974 at the age of 80.

WOMAN'S AUXILIARY

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Mrs. Marvin Levenstein, New Haven

Regional Workshop in Pittsburgh

The 1974-1975 Eastern Regional Workshop of the Woman's Auxiliary to the American Medical Association was held at the Pittsburgh Hilton Hotel, Pittsburgh, Pennsylvania, in late autumn. The Connecticut Auxiliary's State Board was represented by nine members who attended the general workshop as well as individual sessions for chairmen of membership, communications, legislation, AMA-ERF, health education, family health, and community health. There were also individual sessions for state presidents and for presidents-elect, most of which involved discussion about the impending change in auxiliary structure.

The Connecticut participants arrived at the eastern regional workshop on Sunday afternoon, having flown from Bradley Field. In the twenty-fourth floor Presidential Suite, we met the auxiliary's national board members as well as our counterparts from the other thirteen eastern regional states.

Connecticut's Mrs. Norman H. Gardner, first vice president of the national board and chairman of the workshop, presided at Monday's opening session, introducing Mrs. Erle E. Wilkinson, national president-elect, who moderated a "Talk Shop" that included all national board chairmen as well as Miss Hazel Lewis, executive director. The entire group divided into separate specialized "Talk-Ins" for the rest of the morning and afternoon sessions, except for a luncheon program on AMA-ERF for everyone. Following the sessions, a "Walk, Talk, or Shop" time was set aside in our workshop schedules at 4 P.M. I can report that we did all three! Pittsburgh is a uniquely-located city with dramatic hillsides, spectacular metal skyscrapers, and converging rivers crossed by many bridges. It also has excellent shopping and cultural areas.

Later, a reception was held in the hotel's ballroom, the King's Garden, where interesting state AMA-ERF merchandise was on display and available for sale. Dinner followed and was sponsored by AMPAC. Mrs. Daniel Anderson, our eastern regional vice president, presided. She introduced Mrs. John M. Chenault, a member of AMPAC's board of directors, who presented the two speakers for the evening, Robert H. Fry, regional director of the AMA Field Service Department, and Dr. Jack Lewis, chairman of the AMPAC board of directors. Dr. Lewis, accompanied by Mrs. Chenault at the piano, exhorted the assembly in prose and song to become politically involved. After dinner, participants met with their state group for a "State Rap." Mrs. Gardner joined Connecticut's "Rap," encouraging us in our endeavors.

On Tuesday, Hoyt D. Gardner, M.D., a member of the AMA Board of Trustees, spoke at breakfast. He mentioned an anticipated closer amalgamation of the men's association (AMA) with the auxiliary in the future. "The AMA's priority this year is quality health care for all people at a price they can afford," he said, and he mentioned health education, continuing medical education, nutrition, aging, and environment as primary concerns. Dr. Gardner looked forward to the day when every doctor would be a member of organized medicine.

The workshop concluded at noon after final "Talk-Ins" for various chairmen. The workshop experience itself seemed to give those who attended an opportunity to see the auxiliary organization as a whole.

***IMPORTANT INFORMATION:** This is a Schedule V substance by Federal law; diphenoxylate HCl is chemically related to meperidine. In case of overdosage or individual hypersensitivity, reactions similar to those after meperidine or morphine overdosage may occur; treatment is similar to that for meperidine or morphine intoxication (prolonged and careful monitoring). Respiratory depression may recur in spite of an initial response to Nalline® (nalorphine HCl) or may be evidenced as late as 30 hours after ingestion. LOMOTIL IS NOT AN INNOCUOUS DRUG AND DOSAGE RECOMMENDATIONS SHOULD BE STRICTLY ADHERED TO, ESPECIALLY IN CHILDREN. THIS MEDICATION SHOULD BE KEPT OUT OF REACH OF CHILDREN.*

Indications: Lomotil is effective as adjunctive therapy in the management of diarrhea.

Contraindications: In children less than 2 years, due to the decreased safety margin in younger age groups, and in patients who are jaundiced or hypersensitive to diphenoxylate HCl or atropine.

Warnings: Use with caution in young children, because of variable response, and with extreme caution in patients with cirrhosis and other advanced hepatic disease or abnormal liver function tests, because of possible hepatic coma. Diphenoxylate HCl may potentiate the action of barbiturates, tranquilizers and alcohol. In theory, the concurrent use with monoamine oxidase inhibitors could precipitate hypertensive crisis.

Usage in pregnancy: Weigh the potential benefits against possible risks before using during pregnancy, lactation or in women of childbearing age. Diphenoxylate HCl and atropine are secreted in the breast milk of nursing mothers.

Precautions: Addiction (dependency) to diphenoxylate HCl is theoretically possible at high dosage. Do not exceed recommended dosages. Administer with caution to patients receiving addicting drugs or known to be addiction prone or having a history of drug abuse. The subtherapeutic amount of atropine is added to discourage deliberate overdosage; strictly observe contraindications, warnings and precautions for atropine; use with caution in children since signs of atropinism may occur even with the recommended dosage.

Adverse reactions: Atropine effects include dryness of skin and mucous membranes, flushing and urinary retention. Other side effects with Lomotil include nausea, sedation, vomiting, swelling of the gums, abdominal discomfort, respiratory depression, numbness of the extremities, headache, dizziness, depression, malaise, drowsiness, coma, lethargy, anorexia, restlessness, euphoria, pruritus, angioneurotic edema, giant urticaria and paralytic ileus.

Dosage and administration: ***Lomotil is contraindicated in children less than 2 years old.*** Use only Lomotil liquid for children 2 to 12 years old. For ages 2 to 5 years, 4 ml. (2 mg.) t.i.d.; 5 to 8 years, 4 ml. (2 mg.) q.i.d.; 8 to 12 years, 4 ml. (2 mg.) 5 times daily; adults, two tablets (5 mg.) t.i.d. to two tablets (5 mg.) q.i.d. or two regular teaspoonfuls (10 ml., 5 mg.) q.i.d. Maintenance dosage may be as low as one fourth of the initial dosage. Make downward dosage adjustment as soon as initial symptoms are controlled.

Overdosage: Keep the medication out of the reach of children since accidental overdosage may cause severe, even fatal, respiratory depression. Signs of overdosage include flushing, lethargy or coma, hypotonic reflexes, nystagmus, pinpoint pupils, tachycardia and respiratory depression which may occur 12 to 30 hours after overdose. Evacuate stomach by lavage, establish a patent airway and, when necessary, assist respiration mechanically. Use a narcotic antagonist in severe respiratory depression. Observation should extend over at least 48 hours.

Dosage forms: Tablets, 2.5 mg. of diphenoxylate HCl with 0.025 mg. of atropine sulfate. *Liquid,* 2.5 mg. of diphenoxylate HCl and 0.025 mg. of atropine sulfate per 5 ml. A plastic dropper calibrated in increments of ½ ml. (total capacity, 2 ml.) accompanies each 2-oz. bottle of Lomotil liquid.

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454 R

Newer Techniques of Treatment of Sexual Dysfunction

Today's rapidly changing sexual mores may often bring patients to their family physician with questions about their sexuality.

Sex counseling clinics based on the concepts of Masters and Johnson are able to handle only a few hundred couples each year. Few physicians have been exposed to any formal courses in sex education. As such, sexual maladjustment may be a frequent cause of anxiety and depression and the physician should not be uncomfortable in discussing any form of sexual expression. To be an effective therapist requires being at ease and having some knowledge of the problem. The physician should not depend on his own experience and "hang-ups." Because there are not enough sex counselors, the family physician will be called upon increasingly for help. Some familiarity with counseling techniques, starting with the interview of both partners, is essential. To prepare for the role, courses offered by medical schools on the restructuring of sexual attitudes can be very helpful.

There is a wide range of therapy for such problems of sexual dysfunction as impotence, premature ejaculation or orgasmic failure aside from the traditional approach of long-term psychotherapy. A new approach is "pair therapy" following the methods of Masters and Johnson.

RAYMOND C. ANDERSON, M.D.

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BENSON MCGANN, M.D.

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The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiry of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511, (203-865-6822).

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Internal Medicine: Gastroenterology: Available July 1975. Board certified. Presently Fellow at NYU School of Medicine. 28 years old. Contact CSMS—IK.

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Ophthalmology: Will complete residency at Washington Hospital Center, Washington, D.C., in July 1975. Desires group or associate practice. 31 years old. Married. Alan J. Segal, M.D., 9244 Three Oaks Drive, Silver Spring, Maryland 20901

Ophthalmology: Board eligible. Connecticut license. Presently Retina Fellow at Medical College of Wisconsin. Yale and NYU graduate; Tufts-New England Medical Center. Desires to return to Connecticut. Available July 1975. Robert A. Wiznia, M.D., 2532 N. 124 St., Apt. 247, Wauwatusa, Wisconsin 53226.

Orthopaedic Surgery: Board certified in rheumatology and Board eligible in orthopaedics. Available late spring. Trained at Columbia and Harvard. 30 years old. Desires solo, group or associate type practice in larger community. James E. Elbaor, M.D., 75 St. Alphonsus Street, Boston, Massachusetts 02120.

Orthopaedics: Connecticut license, Board eligible. Available in July 1975. Georgetown Medical, Mt. Sinai and Albert Einstein residency. Presently at Bowman Gray School of Medicine in Winston-Salem, North Carolina. Eric Garver, M.D., 260-D Glendare Dr., Winston-Salem. 29 years old. Married. Desires group or associate practice.

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Otolaryngology: Board certified. Connecticut license. Presently in practice. 37 years old. Group or partnership, or solo in community needing ENT coverage. Can be available on short notice. Wishes to return to New England. David J. Langenbrunner, M.D., 103 Turfway Road, Florence, Kentucky 41042.

Otolaryngology: Board certified. Princeton, Pennsylvania Medical. New York University and Bellevue residency. Available with short notice. 30 years old. Married. Wishes to leave N.Y.C. Harvey M. Plasse, M.D., 420 East 55th Street, N.Y.C. 10022.

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Pediatrics: Board eligible. Presently in the Air Force. Available July 1975. 30 years old. Married. Georgetown Medical School. Residency at Albert Einstein College of Medicine. Desires group or associate or institutional practice. Martin Pinsley, M.D., 4516 Shady Lane, Wichita Falls, Texas 76308.

Pediatrics: Board eligible. Presently in Connecticut completing residency program. Chief resident at Burgdorf Health Center's out-patient department in Hartford. Wishes to remain in Connecticut. 27 years old. Married. John Schreiber, M.D., 6-B Wedgewood Drive, Bloomfield, Connecticut 06002.

Pediatrics: Board eligible. Presently in the U.S. Army. Dartmouth Harvard Medical. Children's Hospital in Boston. 29 years old. Available July 1975. Group practice desired. Edward I. Walkley, M.D., 15 5th Artillery Road, Ft. Leavenworth, Kansas 66027.

Pediatrics: Bridgeport native wishes to return to Connecticut. Presently in Air Force. Available August 1975. Board eligible. Group or associate type practice. Medical College of Virginia. Albert Einstein College of Medicine internship and residency. 30 years old. Gerald D. Weintraub, M.D., 7331 E. Tamara Drive, Tucson, Arizona 85730.

General Surgery: Board eligible. Interested in trauma and in peripheral vascular surgery. Wesleyan grad. Pennsylvania Medical. Presently resident in Ann Arbor, Michigan. 2 years in U.S. Army. 31 years old. Married. Group or associate practice desired. John R. Clarke, M.D., 2746 Page Street, Ann Arbor, Michigan 48104.

General Surgery: Board eligible. Connecticut license. Available July 1975. Connecticut native. N.J. College of Medicine and St. Raphael's-Albany Medical Center residency. 32 years old. Kenneth A. Ciardiello, M.D., 30th Field Hospital, Augsburg, Germany, APO N.Y. 09178.

General Surgery: Board certified. 34 years old. Available August 1975. N.Y.U. Medical. Bronx Municipal Hospital Center. Presently in Air Force. Stephen H. Green, M.D., 6938 Post Street, Edwards Air Force Base, California 93523.

General Surgery and Peripheral Vascular: Available July 1975. Board eligible. Active in upper and lower GI fibreoptic endoscopy. Presently in U.S. Army. Steven P. Kahn, M.D., 9634 Basket Ring Road, Columbia, Maryland 21045.

General Surgery: Group or associate practice. Available July 1975. Presently chief surgical resident. Board eligible. Tufts Medical School; Nassau County Medical Center. 29 years old. Married. Peter Salzer, M.D., 200 Carman Avenue, East Meadow, New York 11554.

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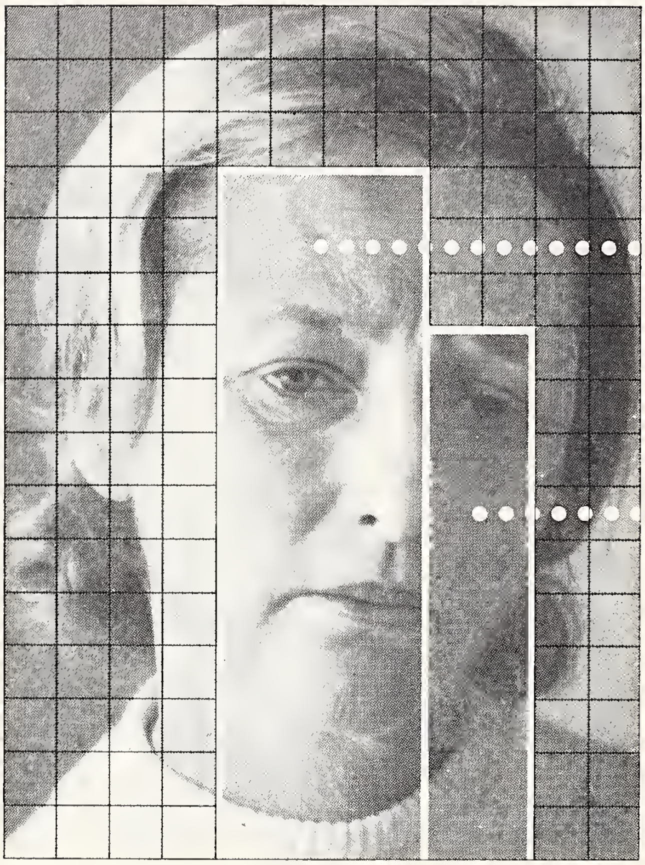
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Diagnosis and Treatment of Hypercholesterolemia and Hypertriglyceridemia

Robert Scheig, M.D.

Introduction

Division of the hyperlipidemias, or as they are now better known, the hyperlipoproteinemias, has become popular in recent years for several reasons. In the first place, convenient methods are now available to measure the levels of serum cholesterol and serum triglycerides and to do lipoprotein electrophoresis. These studies permit one to make a ready diagnosis of a variety of lipid abnormalities. More importantly, however, is the now established fact that there is some type of relationship between hypercholesterolemia and hypertriglyceridemia and the development of atherosclerosis. It is well known that atherosclerosis is now the leading killer in the United States and that atherosclerosis expresses itself in the form of angina pectoris, myocardial infarction, stroke, intermittent claudication, nephrosclerosis, and sudden death. There is strongly suggestive evidence that detection of patients with hypercholesterolemia and hypertriglyceridemia and the correction of these abnormalities will prevent these dire atherosclerotic end points. In this paper, I want to concentrate on three subjects: 1. The diagnosis of hyperlipoproteinemia, 2. the therapy of Type II hyperlipoproteinemia (hypercholesterolemia) and 3. the therapy of Type IV hyperlipoproteinemia (hyperprebetalipoproteinemia) or carbohydrate induced hypertriglyceridemia.

Diagnosis of Hyperlipoproteinemia

Most cases of hyperlipoproteinemia are asymptomatic until one of the serious end points of the disorder is reached. Because history and physical examination are limited in their ability to detect these disorders, it now appears mandatory that each physician screen each patient routinely for lipid abnormalities just as one now routinely gets a hematocrit, a urinalysis or a fasting blood sugar in the course of an annual physical examination. The simplest screening test for cholesterol is, of course, the serum cholesterol level. This can be ordered individually or is now a part of many auto-analyzer methods. Serum cholesterol definitely increases with age in the United States but the question arises as to whether this is a normal phenomenon associated with aging or whether this is a result of environmental factors such as diet which might be detrimental to the individual. Thus the definition of hypercholesterolemia remains in doubt and arbitrary decisions have to be made. There is increasing evidence that any level over 200 plus the patient's age will adversely affect that patient's state of health and should be treated. However, there is no evidence that treating someone past the age of 75 when first diagnosed results in any increase in life expectancy. There is some preliminary data that the familial form of hypercholesterolemia can be detected at birth by measuring the level of cholesterol in umbilical cord blood. It has been found that normally this level is below 100 mg. per hundred ml. and that patients whose level is over 100 mg. per 100 ml. will develop hypercholesterolemia within the first year or two of life if fed a normal diet. These individuals will also be found to have at least one blood relative who has hypercholesterolemia. Although more studies must be done, these data are strongly suggestive that we might have an excellent screening test to detect what appears to be a rather common genetic disorder appearing in somewhere around 1/2 - 1% of the population.

The upper limit of normal for serum triglyceride levels is more uniformly accepted and appears to be 150 mg. per 100 ml. This test is not as readily available as is the serum cholesterol measurement but fortunately there is a simple test that can be substituted which, in this day of increasing medical costs, can be performed free of charge for any patient. Very simply when one draws blood and separates off the red cells if the serum is in any way turbid, one can be sure that the serum triglyceride level is greater than 400 mg. per 100 ml. If one takes that same serum and places it in the refrigerator (not the freezer compartment) overnight, any turbidity detected the following morning indicates that the serum triglyceride level is greater than 250 mg. per 100 ml. Obviously the patient must have been fasting. While this refrigerator test will not detect all patients with hypertriglyceridemia, it will detect most. This refrigerator test has an additional benefit to it in that one can often avoid lipoprotein electrophoresis. Thus, if the following morning all turbidity is at the top of the tube and underneath the

---

DR. ROBERT SCHEIG, Professor of Medicine and Head, Division of Gastroenterology, University of Connecticut School of Medicine. Chief of Medicine, Newington VA Hospital, Newington, Conn.

serum is clear, one can easily make the diagnosis of Type I hyperlipoproteinemia (hyperchylomicronemia or fat-induced hyperlipoproteinemia). If the tube is uniformly turbid, then one is reasonably sure that one is dealing with a Type IV hyperlipoproteinemia. If, on the other hand, the tube is turbid but it is more turbid at the top than at the bottom, then one can establish the diagnosis of Type V hyperlipoproteinemia. This test will not discriminate patients with Type III abnormality but this disorder has been described in only some 60 patients and, since most patients with this disorder have plane xanthomata on the palms of their hands and the soles of their feet and tuberoeruptive xanthomas on the elbows, one is not missing much in not going to the expense of obtaining lipoprotein electrophoresis in most patients.

There are a few important points that must be remembered. The diagnosis is made before therapy is instituted and while the patient is on his usual diet. The patient absolutely must be fasting for a minimum of 12 hours prior to determining serum triglycerides levels. Moreover, when following patients with hypertriglyceridemia, determinations must also be performed when the patient is fasting. It is not crucial to obtain fasting blood when measuring serum cholesterol since dietary cholesterol equilibrates quite slowly with serum cholesterol. Finally, because there is a significant frequency of laboratory error and a significant diurnal variation, and because not all patients reliably report they have fasted, no patient should be started on therapy until at least two and preferably three serum lipid levels have been obtained at least a day apart. Remember that these patients usually are being committed to a lifetime of therapy once the diagnosis of hyperlipidemia has been made so that the physician must be absolutely certain of the diagnosis.

Type II Hyperlipoproteinemia

Hypercholesterolemia has been related to atherosclerosis for longer than any of the other hyperlipidemias. While a goodly proportion of these cases are familial due to a decreased number of receptor sites for low density lipoproteins in peripheral tissues, it is crucial to remember that there are a number of causes other than this inherited defect. Thus, in the routine evaluation of patients with hypercholesterolemia, the following points must be kept clearly in mind.

1. Dietary causes: Increasing evidence points to the fact that it is not the amount of fat in the diet that is related to hypercholesterolemia but the type of fat. Specifically, saturated or hard fat increases serum cholesterol levels and so does the amount of cholesterol in the diet. Polyunsaturated fat, on the other hand, causes serum cholesterol levels to fall. Monounsaturated fat (the common example of which is olive oil) has no effect on serum cholesterol levels. The simplest way to take a dietary history is to recall that over 50% of the fat that is consumed in the United States is consumed as fat per se, i.e., in the form of lard, Crisco, butter, salt pork—all saturated fats, or in the form of corn oil, safflower oil—all polyunsaturated fats. The easiest question to ask is what type of fats are used at home in cooking. Recall, however, that the term vegetable oil would include coconut oil which is a highly saturated fat. Also that the margarines on the market vary greatly in polyunsaturated fat content and that the only way to be sure a margarine has a high content of polyunsaturated fat is if the first ingredient listed on the label is either corn oil, liquid corn oil, safflower oil or liquid safflower oil (not partially hardened oil). In regard to cholesterol in the diet, probably the commonest sources are egg yolks and whole milk and things made of whole milk such as cheese, butter and ice cream. Organ meats such as brains, sweetbreads, liver, kidney are extraordinarily high in cholesterol, while shellfish such as lobster, shrimp, oysters and clams, if consumed in large quantity, will also add up.

2. Genetic: It is crucial to obtain a family history on all patients and questions concerning angina, sudden death, heart attack and stroke in relatives are obvious ones. Other questions could include whether or not any relatives have yellow spots on their eyelids (xanthelasmas) or other forms of xanthomas.

3. Myxedema commonly is associated with hypercholesterolemia and all patients should have a thyroid screening test.

4. Hypercholesterolemia is common in diabetes mellitus and a fasting blood sugar or preferably an oral glucose tolerance test should be obtained on all patients.

5. The nephrotic syndrome is associated with hypercholesterolemia and a urinalysis looking specifically for protein should be performed.

6. Hypercholesterolemia is seen in biliary obstruction and, at the very least, the eyeballs should be looked at for jaundice.

7. Hypercholesterolemia is seen in pancreatitis and a history of abdominal pain should be sought. If present, amylase and lipase determinations should be done.

Once this diagnostic workup has been accomplished, any of these underlying disorders should be treated first. Appropriate dietary therapy should be instituted which essentially means a diet high in polyunsaturated fat, low in saturated fat, and low in cholesterol. Moreover there is evidence that, if patients are overweight, decreasing weight to the ideal level will lower serum cholesterol. Should these measures fail, there are three drugs which are commonly available for therapy. Cholestyramine is the most effective serum cholesterol lowering agent. This anion exchange resin is now marketed under the trade name Questran by Merck, Sharp & Dohme and is available either in 4 gram foil packets or in bulk in a tin—the latter being less expensive. Patients normally are instructed to take 4 grams 3 times daily. This is most easily taken mixed in some fruit juice or applesauce. Doses as high as 36 gms. daily have been given by some, but doses larger than 24 grams daily are routinely associated with the development of steatorrhea. D-thyroxine (marked by Flint Labs. as Choloxin) is the dextroisomer of the native thyroid hormone L-thyroxine. Ostensibly, this isomer has equal cholesterol lowering properties to L-thyroxine with less hypermetabolic effects. The initial dose is 2 mg. daily and this is increased every six weeks until as much as 8 mg. are taken daily. This drug is absolutely contraindicated for patients with angina or who have had a myocardial infarction. Clofibrate (Atromid marketed by Ayerst) has recently had a resurgence of popularity for the therapy of hypercholesterolemia. This popularity is based on a prospective controlled study which indicated that, irrespective of its effects on serum lipid levels, clofibrate does decrease the incidence of new angina or myocardial infarction or sudden death in patients who have known atherosclerotic heart disease. There is also convincing laboratory evidence that while clofibrate does not immediately lower serum cholesterol levels, it does markedly diminish the body pool of cholesterol within 6 weeks. At present it is not known whether serum cholesterol levels or body pool cholesterol levels are more related to the development of atherosclerosis. Clofibrate is given as a 500 mg. capsule and the dosage is 2 grams daily (either 2 capsules twice daily or 1 capsule 4 times daily).

Type IV Hyperlipoproteinemia

Type IV hyperlipoproteinemia is also a genetic disorder although the heredity has not been well worked out. Again up to 1% of the population may be involved. No test is yet available to detect patients at birth. Pretty much the same thing can be said in regards to underlying causes as we have already said about hypercholesterolemia with the following modifications or additions. Regarding diet, the amount of cholesterol does not appear to be important but the amount of saturated and polyunsaturated fat does. Even more important, however, appears to be the amount of carbohydrate and ethanol which is contained in the diet since these two calorie producing foods, if taken in excess, will always produce hypertriglyceridemia. Moreover, there appears to be a relationship of this lipid disorder to recent increases in weight. Hypertriglyceridemia is commonly seen in chronic nephritis so that part of the routine screen should be a BUN. Hypertriglyceridemia is also seen in association with pancreatitis, the nephrotic syndrome, diabetes, and rarely in patients with myxedema.

Therapy of Type IV hyperlipoproteinemia again is first directed toward any underlying causes and secondly towards the diet. Here weight reduction, if the patient is overweight, is crucial, as is restriction of carbohydrate and ethanol intake and a substitution of polyunsaturated for saturated fat in the diet. If dietary measures are ineffective the drug of choice is clearly the administration of clofibrate.

The preceding information should permit any physician to handle the vast majority of patients with lipid abnormalities. The only errors that tend to be made are omission of some aspects of the workup or an inadequate grounding in dietary therapy. If the reader is interested in greater detail regarding the diet, or is unwilling to spend the time to go into details of the diet with the patient, diet manuals are available from the National Heart and Lung Institute, National Institutes of Health, Building 31, Room 4A10, Bethesda, Md. These handbooks for physicians and for patients are entitled "The Dietary Management of Hyperlipoproteinemia" and are quite readable and understandable by patients and should be utilized.

Inguinal Hernia Repair

Donald R. J. Welsh, M.D.

External hernias head the list of common surgical conditions in the abdominal area. Approximately 500,000 herniorrhaphies are performed in North America each year. Roughly 1% of these hernia repairs—5,043, to be exact—were performed at Shouldice Hospital in 1973, extending our series since 1945 to more than 85,000.

Early ambulation and improved anaesthetic techniques have reduced the mortality rate for elective hernia repair to such a low level that this is no longer a deterrent to surgery at any age.[1] There does, however, continue to be an appalling morbidity associated with hernia in terms of restricted job capacity and loss of time from work, both before and after surgery; this is mainly due to outmoded concepts in both treatment and rehabilitation. Unacceptably high recurrence rates result in a repeat of the problem, often on a more serious scale.

The accompanying table shows the principal hernia types we have encountered during the past 7 years, in the descending order of their frequency. As might be expected, inguinal hernias make up 94% of the series—the indirect variety nearly twice as common as the direct. The indirect hernias included 1,956 sliding hernias—an incidence of approximately 11%; these figures are not shown in the table.

The percentage of each type that were already recurrence problems is indicated in the third column of the table—nearly half the femoral hernias, 19% of the direct inguinal hernias, and even 9% of the indirect inguinal hernias. These figures undoubtedly exaggerate the prevailing general recurrence rates, since our reputation as specialists in this field does attract difficult cases, but they do emphasize the problem that exists.

The last column in the table shows the number of co-existing secondary type hernias discovered at operation; these were usually masked by the larger principal type diagnosed at the clinical examination. It is obvious that failure to identify and deal with these hernias at the primary operation could result in a subsequent 10% recurrence rate due to this factor alone.

Our overall recurrence rate for all types of hernias repaired prior to 1971 is shown in the recurrence graph. The figures are based on as thorough a follow-up as possible up to March, 1973. Over the years the recurrence rate for the initial 1945 series has gradually risen to nearly 18%. The period from 1945 to 1951 was a formative one, during which most of the innovations and refinements in our technique were introduced; the graph shows the accomplished reduction in the recurrence rate to 3% for the 1948 series and to 1% or less for the 1952 and subsequent series. These figures include femoral, incisional, and recurrent inguinal repairs; if only primary inguinal repairs were considered our recurrence rate for the past 20 years would be less than 0.5%.

SHOULDICE HOSPITAL — 1967 TO 1973 (7 YEAR) SERIES

HERNIA	PRINCIPAL TYPE			SECONDARY TYPE
	% of Series	*Number*	*% Recurrent*	*Number*
Indirect Inguinal	59.57	17,357	9.0	602
Direct Inguinal	34.57	10,073	19.0	1,320
Femoral	1.98	576	47.2	139 (sac) 633 (fatty)
Incisional	1.70	495	30.7	13
Umbilical	1.30	379	9.5	86
Epigastric	0.69	202	9.9	14
Miscellaneous	0.19	55	10.9	101
	100.00	29,137	13.6	2,908

The desirability of a thorough and prolonged follow-up and our methods of carrying this out have been discussed in a recent article.[2] A two year follow-up is the absolute minimum in assessing one's results; missed hernias and inadequately repaired hernias will usually reveal themselves within this period. Additional recurrences, due to inadequate reinforcement of adjacent areas or to undue strain placed upon these areas by the primary repair, often take longer to develop and show up unexpectedly in subsequent years; these are classed as recurrences because they occur within the scope of the first operation.

From the clinical, operative, and follow-up statistics amassed by our group and 18 years personal experience, I am able to draw certain conclusions and offer some definite recommendations. I will stress what we consider to be the "keys" to effective inguinal hernia repair, comment upon some of the alternatives, and conclude with some remarks regarding postoperative management and rehabilitation.

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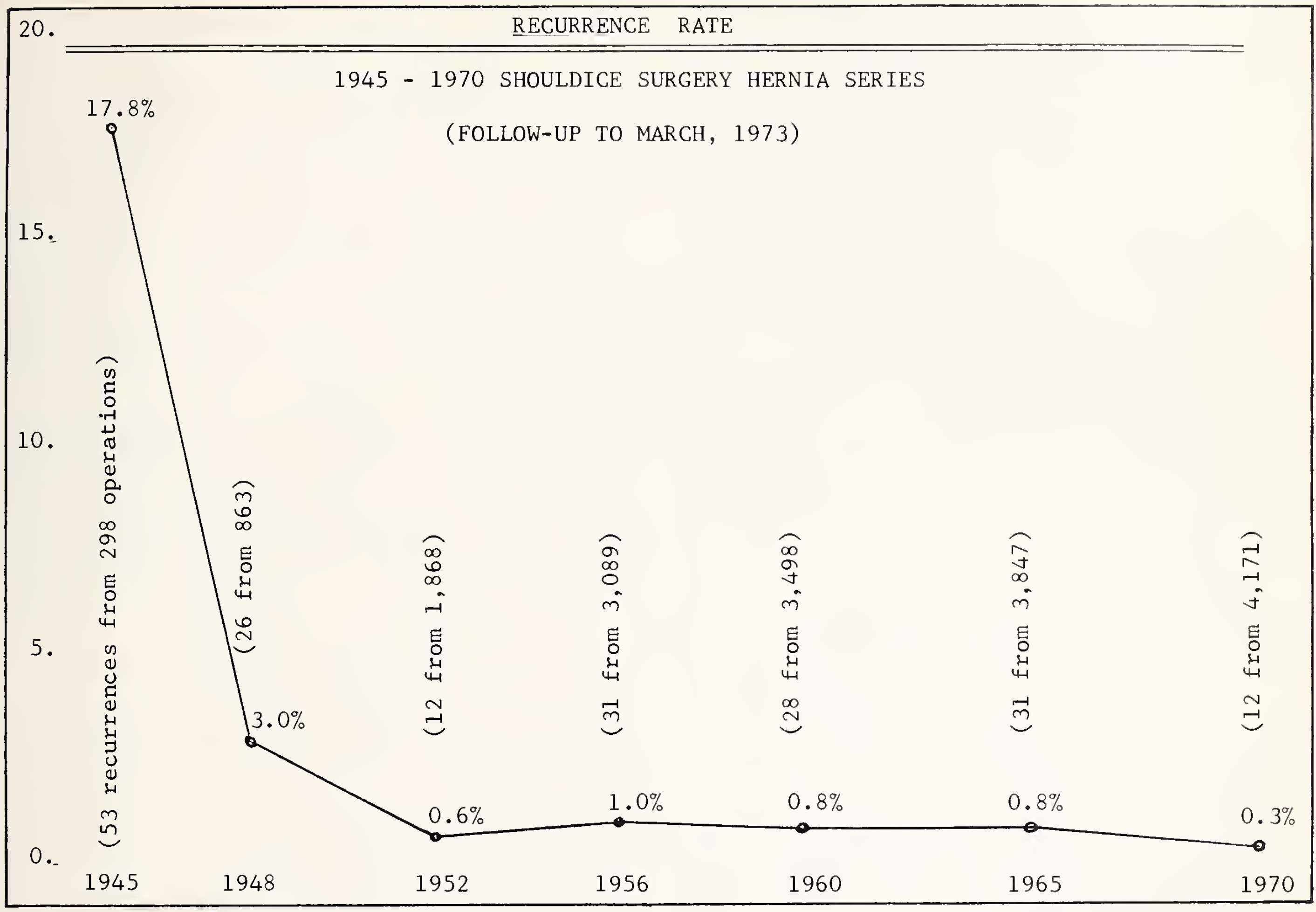

Laying the Groundwork

Recognition of the anatomy, both normal and abnormal, and thorough dissection and exploration of the inguinal region are absolutely essential; a high proportion of failures can be attributed to inadequacies in this phase of the surgery. In the past, most writers have placed too much stress on the specific repair technique they favour, and too little on the importance of laying the proper groundwork for the repair. There has been a resultant tendency for surgeons, who have been achieving mediocre results, to switch to each new repair described, expecting it to be the magic solution; unfortunately, their results do not improve, because they continue to overlook basic errors and omissions in their technique.

There is a simple but frequently overlooked preparatory measure which makes hernia surgery easier for both the surgeon and the patient, and reduces the risk of recurrence. If the patient is overweight—as nearly half of them are—he must be instructed to reduce at least half this excess weight by dieting prior to admission to hospital; if he will not cooperate, you should refuse to proceed with an elective repair. Better quality tissues under less tension permit a more effective overlapping type repair and produce a stronger scar; the patient experiences less discomfort during convalescence—an additional benefit which he should appreciate.

We recommend an oblique incision extending to the level of the pubic tubercle medially and long enough to provide ready access to both the inguinal and the femoral region. You should split the external oblique aponeurosis to a point at least one inch lateral to the internal ring; if you do not, you are likely to miss an occasional unsuspected Spigelian or interstitial hernia. Excision of the cremasteric muscle and vessels in the inguinal canal area eliminates troublesome oozing, facilitates exposure of the transversalis fascia, and permits accurate fascia-to-fascia repair. We adopted this practice in 1952 and there have been no demonstrable harmful effects.

Regardless of the principal type of hernia apparent, and before any thought is given to the appropriate repair technique, the entire groin region must be explored and the internal inguinal ring and canal floor areas thoroughly dissected out. Indirect inguinal recurrences can be virtually eliminated if a few simple precepts are observed; we have had only 12 recurrences develop at this site in our series of nearly 80,000 inguinal repairs and the majority of these followed repairs performed prior to 1952.

Internal ring dissection is an obvious necessity when a true indirect sac or sliding hernia is evident. If this is not the principal hernia site it is equally important to identify and free the "peritoneal protrusion" on the superior surface of the spermatic cord—a constant anatomical entity which has not received the attention it warrants. This protrusion should not be termed an indirect hernia unless it extends further than one-half inch beyond the transversalis fascia level, but an indirect recurrence may follow, particularly when the Halsted type repair is used, if it is ignored. The spermatic cord and peritoneum, whether the latter is a true hernia or normal protrusion, must be completely freed from the encircling cuff of transversalis fascia at the internal ring. The hernia or protrusion of peritoneum must then be freed from the spermatic cord to a level that will permit reduction proximal to the transversalis fascia at the ring. "High ligation" is an outmoded precept which should be abandoned since it is neither necessary nor particularly desirable and can create complications; redundant empty hernia sacs should be removed at a convenient level but there is no need to even open a short broad sac or sliding hernia.[3]

The canal floor poses a more difficult problem. Direct hernias are more prone to recur; secondary type hernias are commonest in this area, and it has been recognized for many years that direct hernias may crop up later in patients who have had indirect hernias repaired. Blind plication of the transversalis fascia is an easy but ineffective procedure. You must expose the entire canal floor and split the transversalis fascia—to the pubic tubercle when a direct hernia is present, and at least halfway when it does appear intact, to permit adequate exploration. The direct hernia or preperitoneal fatty tissue can then be freed away from the deep surface of the transversalis fascia and the edge of the rectus sheath visualized above. If there is a direct hernia, the excess attenuated fascia should be trimmed from one or both flaps; if the peritoneal sac is large or has a constricted neck, it should be opened from its lateral aspect, to avoid entering the urinary bladder which may form part of the medial wall, and the redundant sac removed. Canal floors that appear to be intact and reasonably strong when the patient is supine and relaxed frequently prove to be thin and lax when they are properly explored. The lateral half of the floor is at best a weak structure; if no secondary or incipient hernia is discovered on exploration, at least the stage is set for a more effective prophylactic repair.

The femoral region should be explored next. This can be done readily from above by inserting a finger tip under the lower flap of the split transversalis fascia; the region should also be checked visually from below by incising the fascia of the thigh, parallel to the inguinal ligament, to expose the femoral sheath and pectineus fascia. Our table shows a 3% incidence of secondary femoral hernias uncovered at inguinal hernia operations, and prophylactic femoral repair was considered advisable in a significant number of additional cases.

Spigelian and interstitial type hernias are uncommon but embarrassing to miss. The exposed surface of the internal oblique muscle superior and lateral to the internal ring should be inspected. If your earlier dissection at the internal ring was adequate you should be able to sweep your fingertip beneath the transversalis fascia in this area of the muscle wall to test its strength. If the muscle wall, lateral to the ring, is of poor quality it is advisable to split it the necessary inch or so to reach healthier muscle; the end result will be a more laterally positioned internal ring and a longer canal floor.

The Inguinal Repair

Most of the techniques described in the literature will give reasonably satisfactory results if the preceding dissection has been adequate and if the repair is competently performed. I do not propose to outline the Shouldice repair in detail; it has been described in recent articles.[4] [5] We advise a combined direct - indirect repair in every instance, overlapping the layers of fascia and muscle in their natural sequence.

The key to the repair of the internal ring area is closure of the defect in the transversalis fascia medial to the cord after the hernia, sac stump, or peritoneal protrusion has been completely freed and reduced. Too tight a closure is likely to produce testicular atrophy or hydrocele formation. You should be able to introduce curved Kelly forceps through the closed ring without difficulty; this also reveals any significant bleeding deep to the closed transversalis fascia, and any redundant length of spermatic cord can be reduced through the ring at this stage. Transection of the spermatic cord, with or without orchidectomy, for the purpose of complete closure of the internal ring is an unnecessary mutilating procedure.

We commence the repair of the direct region by overlapping the transversalis fascia, but one should not depend on this layer alone to provide sufficient strength. Do not hesitate to make use of the internal oblique muscle tissue available; the theory that this should be avoided to preserve a "shutter mechanism" is a goal unlikely to be achieved—the scarring and adhesions unavoidably initiated by adequate dissection will probably nullify movement between planes in this area. A relaxing incision is sometimes helpful, but routine use can be avoided if you make your overweight patients diet prior to surgery. Repair of the direct inguinal region via the "preperitoneal approach" is not feasible in our opinion; we do *not* recommend this approach.

We maintain the obliquity of the inguinal canal and the normal anatomical relationships of the spermatic cord. If the reconstruction of the external ring beside the pubis will constrict the spermatic cord, a more lateral position nearer to the internal ring should be selected. There is usually sufficient external oblique aponeurosis to permit an overlapping type of closure.

We strongly advise the use of some type of nonabsorbable suture material. Our personal preference is fine monofilament stainless steel wire used in continuous fashion. Mesh prostheses may be the only solution in some very difficult cases, but we decry their routine use.

Postoperative Management

Immediate ambulation, discharge from hospital on the third postoperative day, and permission to resume activity as soon as desired are principles we have followed for nearly 30 years. The present Shouldice Hospital, completed in 1969, is an 84-bed private hospital situated in Thornhill, Ontario, a northern suburb of metropolitan Toronto; our practice is restricted to hernia surgery and this hospital was designed to minimize hospital atmosphere and encourage maximum ambulation. Patients go to the dining room for their meals and participate in supervised group exercises, commencing the day following surgery; when weather permits, outdoor recreational facilities are available. Management of hernia patients as a group with these facilities certainly has its advantages over the general hospital atmosphere and setup; you should enlist the help of your physiotherapy department, if necessary, to achieve the main goal of early and active ambulation.

We use Michel clips for skin closure. These are loosened and alternate clips removed on the first postoperative day; the remainder are removed on the second postoperative day and usually no further dressing is required. If the patient requires bilateral repair, the second operation is performed 48 hours after the first unless there is some contraindication. Staging the two repairs gives you the opportunity to talk to the patient and review the situation between operations; dependent upon the patient's state of health, tension in the tissues, and the difficulties encountered at the first operation, it is sometimes wiser to defer the second operation —particularly when the second hernia is small and not troublesome.

We have used local infiltration anaesthesia for 98% of our inguinal hernia repairs; this is not essential for the repair itself but it does minimize complications and provide certain advantages. It allows demonstration of the hernia and testing of the repair, if desired, while the operation is in progress. It is a safer anaesthetic for the elderly and for patients with cardiac or pulmonary disease. It permits the earliest possible ambulation— the ability to walk away from the operating table, and deep breathing and coughing without discomfort in the immediate postoperative period; the incidence of phlebothrombosis, embolism, and pulmonary atelectasis is virtually nil when this regimen is followed.

Although 18% of our patients are over age 65, placing them in the "prostate age group," we rarely encounter any postoperative urinary retention problems. Early ambulation has reduced this problem to a considerable degree in all hospitals; the combination of early ambulation and local infiltration anaesthesia seems to have eliminated it in our hospital. If there is a palpable distended urinary bladder we do defer the hernia surgery until the cause of this has been investigated and treated. We do not consider a history of mild symptoms of prostatic obstruction, or the presence of an enlarged prostate gland, a deterrent to proceeding with the hernia repair; restoration of a strong functional lower abdominal wall often alleviates such symptoms.

We do not discharge our patients from hospital until the third postoperative day. In this respect we are more conservative than the advocates of a one-day stay; we feel that the three days are useful in setting the pattern for convalescence, and any unanticipated complications can be dealt with on the spot. The patient can carry his baggage and drive his car when he leaves hospital; he can return to his home, regardless of the distance, and no further office visit is normally necessary.

We do not place any restrictions on activity following discharge but do advise the patient to avoid soaking the incision during the first week. We warn the patients that prolonged activity may cause fatigue during the first two weeks and that heavy lifting is likely to cause some discomfort during the first three to four weeks. Four weeks is the maximum normal convalescence that we will authorize; self-employed patients frequently resume work immediately. Regardless of our advice, many of the larger American industries refuse to allow their employees to return to work sooner than six weeks or even longer after hernia surgery, adhering to recommendations laid down thirty to forty years ago.

A prolonged convalescence with carefully graduated resumption of activities is not likely to enhance a poor repair. Elective effort, particularly if it is scaled to comfort level, creates less strain than an inadvertent cough or sneeze. Early resumption of strenuous activity will not damage a good repair; it convinces the patient that he will have no permanent disability and displays the surgeon's confidence in his work.

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Current Problems in Renal Transplantation

Bernard Lytton, M.B., F.R.C.S., and Martin Schiff, Jr., M.D.

Renal transplantation and chronic hemodialysis have now become accepted methods of treatment for patients with chronic renal failure, and have greatly improved the outlook for such individuals. At the present state of our knowledge, however, the problem is by no means solved. Patients who are maintained on chronic hemodialysis must spend 15 to 30 hours per week attached to the dialysis machine, which severely limits their mobility and drastically alters their life style. In addition, the constant need for ready access to the peripheral circulation constitutes a separate and often serious problem. Arteriovenous shunts and fistulae have a limited functional life span, often require periodic revision resulting in functional loss of one or more extremities, and have, on occasion, resulted in an inability to continue with hemodialysis.

The majority of patients on long-term dialysis become severely anemic and are subjected to permanent dietary and fluid restrictions, which eventually become irksome. These restrictions are particularly onerous in children on dialysis in whom severe growth retardation often develops. In addition, difficulties with severe hypertension, peripheral neuropathy, skeletal deformities, pruritis and bleeding diathysis may also eventually become manifest after varying periods of time on dialysis. Emotional dependence, either on in-hospital staff or on relatives trained to assist with home dialysis, is an extremely common characteristic of these patients. Overall only about half the patients become successfully rehabilitated, return to work, and make a satisfactory adjustment to their situation, but many become chronic invalids.

Approximately 15% to 20% of patients entering dialysis die during the first year of treatment, and thereafter there is a rather steady mortality of 10% per year.[1] The experience at the Yale-New Haven Medical Center and West Haven Veterans Administration Hospital tends to parallel the national experience; only 50 of 86 patients placed on dialysis during the first 5 years of the program remained alive at the end of that period of time. Furthermore, survival by a patient for the first few years following institution of dialysis, does not necessarily portend a long-term success, since it has been found that accelerated atherosclerosis later becomes a major risk.[2] Thus, while chronic dialysis is certainly an acceptable treatment for an otherwise fatal disease, it can, for many patients, only be considered as a holding action until the patient can receive a kidney transplant.

At the present time, although the results in terms of patient survival in recipients of cadaveric renal transplants are not quite as good as chronic dialysis, the quality of life is vastly improved for those with a successful graft. Patients who receive a cadaveric renal transplant have almost a 50% chance of surviving with a functioning graft for 2 years; after this time a number develop chronic rejection which reduces the percentage of functioning grafts to approximately 30% at the end of 5 years.[3] Those patients with a successful graft once again become independent individuals and lead normal lives. They do need to remain on small doses of immunosuppressive drugs, and be evaluated at regular intervals.

Patients who receive a kidney from a living related donor have a better prognosis. Approximately 70% survive with good renal function for 2 years and 55% are alive with functioning grafts after 5 years.[3] Most patients who receive and then reject a graft return to hemodialysis and await receipt of a second transplant if and when this becomes available. The remainder die from complications associated with the graft and immunosuppressive therapy.

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108 patients have undergone renal transplantation at the Yale-New Haven Medical Center during the past 6 years; 3 patients have received a second graft, making a total of 111 transplants. Of these, 27 were from living related donors and 84 from cadaveric donors. 13 of the recipients were children under 16 years of age, the youngest being 18 months. Overall, 50 patients are alive with a functioning kidney (1-70 months), 27 have been returned to being maintained on chronic hemodialysis, and 31 have died. The majority of deaths occurred during the first 2 years of the program before experience had led to the earlier recognition of an irreversible rejection and earlier graft removal. In addition, many of the earlier patients would now be considered unsuitable for transplantation.

A review of the results recorded in the Human Renal Transplant Registry which has collated the data from over 12,300 transplants performed in the United States, Canada, Europe, and Australia, indicates that while an improvement in the results of cadaveric renal transplantation occurred progressively until 1970, this has now plateaued and the results have remained much the same over the last 4 to 5 years. It would seem that optimal use is now being made of the presently available methods of immunosuppression; Azathioprine (Imuran), steroids, irradiation, and anti-lymphocyte globulin (ALG), and that any further improvements will result from new methods for control of immunologic rejection. There are 3 major areas in which further research needs to be done in an attempt to achieve this goal; renal preservation, improved tissue matching, and the induction of specific enhancement.

Renal Preservation

A cadaveric kidney can presently be maintained up to 48 hours after removal from the donor. This is accomplished by perfusing the kidney at 7° C. with cryoprecipitated plasma using a pulsatile pump and a membrane oxygenator. This technique was originally developed almost 7 years ago[4 5] and several types of perfusion machines are presently in use. The one used at this Medical Center is the *Waters* machine, developed at the University of Minnesota, which comes in both a static and portable model. The advantages of renal preservation are several; first, it allows sufficient time for tissue typing to be performed so that the best possible donor-recipient match can be found. Secondly, it allows time for preparation of the recipient, including dialysis if necessary, and for transportation of the kidney to a distant place where the recipient might be located. Thirdly, perfusion characteristics of the kidney such as flow rate and peripheral resistance, can be monitored over a period of time, thus indicating whether it is suitable for transplantation. If these factors are not satisfactory, the kidney should not be used; indeed, approximately 15% to 25% of kidneys placed on perfusion are discarded, obviating the unhappy experience of implanting a kidney that has a poor vascular system and will never function satisfactorily. It is hoped that with further research the prolongation of successful renal preservation will allow performance of more sophisticated methods of tissue typing and will untimately improve graft survival.

Tissue Typing

It has been found that a single chromosomal locus, known as the HLA locus, is responsible for carrying the major antigens responsible for histocompatibility in the human. This locus is thought to be divided into 3 serologically defined sub-loci and 1 lymphocyte defined locus known as the LD locus. The HLA locus is composed of a pair of alleles, one being inherited from each parent. There are known, at present, 13 antigens identified with the first sub-locus and 14 with the second sub-locus, one antigen from each sub-locus being inherited from each parent. Thus, one individual may express 4 different serologically defined antigens at the first and second sub-loci. It is thought that the LD locus tends to segregate with the second HLA sub-locus so that matching at this sub-locus is probably more important than at the first. The third sub-locus has 3 antigens associated with each allele but antisera for these antigens are not yet readily available. There are probably additional antigens present at the HLA locus, but at present these have not yet been identified by any known antisera. Many of the antisera are still not monospecific and cross-activity does occur. This accounts in part for some of the problems encountered in HLA matching in unrelated donor-recipient situations in an outbred population. There is increasing evidence that lymphocyte defined histocompatibility is more important than obtaining a good serologic match, but at present this can only be determined when there is a living donor, as the test takes 5 to 7 days to perform and a cadaveric kidney cannot be maintained for that period of time. New methods for performing the mixed lymphocyte culture (MLC), which quantitates compatibility at the LD locus, are being developed and it is probable that it will be possible to perform this test within a 24-hour period in the near future. This should improve our ability to effectively match potential recipients with available cadaveric donors.

A serologic cross-match is always performed immediately prior to transplantation in order to determine whether any cytotoxic humoral antibodies are present in the serum of the recipient which will kill donor lymphocytes. This form of presensitization, which may occur as a result of previous blood transfusions, previous exposure to HLA antigens from a prior graft, or from multiple pregnancies, results in a hyperacute rejection of the transplant. This is manifested by rapid intravascular thrombosis in the transplanted kidney which occurs within several minutes to several hours after re-establishment of the vascular supply. Both anticoagulants and immunosuppressive agents are ineffective in reversing this type of rejection.

Specific Enhancement

It has been found that many patients with a successfully functioning graft have persistence of their cell mediated immunity; that is, the ability of their lymphocytes to destroy cells derived from the graft, which may be quantitatively measured using tissue culture techniques. This cell destruction can be prevented by adding the patient's own serum, an effect which has been shown to be due to the presence of a blocking factor, probably an antigen-antibody complex, which prevents destruction of the graft by sensitized lymphocytes. This cell mediated immunity of the patient's lymphocytes, however, does not seem to persist indefinitely, and in the later stages following successful transplantation, there seems to be an inability of the recipient's lymphocytes to respond to antigenic stimulation. This has recently been shown to be so for grafts successfully functioning 3 years later, when lymphocytes of such patients are found to be no longer capable of being stimulated in MLC. This finding would help to explain the greatly increased incidence of tumors in immunosuppressed allografted patients.[6, 7] The inability of the lymphocytes to respond to the presence of a new tumor antigen represents a loss of the immunological surveillance mechanism which is thought to play a large part in tumor control. Therefore, it would be of considerable advantage if the patient's cell mediated immunity could be preserved and blocking factors developed which are antigen specific; this would enable the patient to have specific tolerance for the grafted kidney but would at the same time obviate an associated lack of immunological responsiveness against other foreign antigens such as microorganisms or tumors. Statistics derived from over 7,000 renal transplant recipients indicate that the incidence for spontaneous neoplasms is 80 times as great as that occurring in age matched controls.[8] It is of interest that about 50% of these tumors are of reticuloendothelial origin and the remainder are a variety of epithelial and mesenchymal tumors. Additional research into the mechanism of the production of blocking factors and their chemical composition will be needed before these problems can be solved.

Cadaveric Donors

One of the outstanding problems facing many transplantation programs is the shortage of suitable cadaveric donors. Donors are restricted to patients who have sustained intracranial catastrophies or have been involved in a fatal accident; they should be under 50 years of age, have no evidence of malignancy, sepsis, or vascular disease. Demographic analyses of deaths in urban populations have shown that sufficient donors should be available.[9] There has always been some natural reluctance on the part of an attending physician to broach the subject of kidney donation to the family of the potential donor at such an emotionally charged and sensitive time. This reluctance on the part of the physician must be overcome and a broad public education program undertaken if the large number of patients awaiting the transplantation are to be satisfactorily treated.

The potential donor's physician would be relieved of the onus of having to approach the family by arranging for another physician or member of the clergy to undertake this task. Public education will have to involve a reorientation toward the traditional definitions of death and an understanding of the need for cadaveric organs, the procurement of which is not incompatible with respect for the dead.

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Sequential Cryotherapy for Prostatic Carcinoma: Does it Palliate the Bone Pain?

Anthony H. Horan, M.D.

Abstract—As a presumed empirical form of immunotherapy for painful osseous metastases from carcinoma of the prostate, two five minute freezes separated by a five minute warming period were applied to the primary tumor in the prostate with the Linde CE 4 cryogenic unit and LR-60 prostatic cryoprobe in six patients.

A remarkable subjective remission of pain from three months to three years was noted. Objective results were discontinuation of intra-muscular narcotics, weight gain and discharge from the hospital. Further trials in general hospitals appear justified by the simplicity, lack of complications, and low cost of the treatment.

Introduction

While immunotherapy for disseminated neoplasm has been available for several years in specialized cancer hospitals, few regimens which are practical for use in general hospitals have been described.

From 1970 to the present, the Linde cryoprobe has been used at The Francis Delafield Hospital, a specialized municipal cancer unit in New York City, for the relief of bone pain of disseminated carcinoma of the prostate as an empirical form of presumed immunotherapy. The therapy is based on the demonstrated production of specific prostate antibodies by Barnes, et al, induced by freezing.[1] In addition, previous reports of the relief of bone pain by cryotherapy have appeared.[2 4] The purpose of the present report is to confirm and extend previously published series so that the simplicity, economy and complications of this treatment may be compared to other methods of palliation each of which has its advocate. A sequence of palliative modalities is suggested.

Materials and Methods

From a series of eighty patients treated for bone pain with cryotherapy, the six patients treated or personally examined by the author were included. The prostate was routinely biopsied before insertion of the cryoprobe. In the larger glands, the transurethral route was used to obtain chips and to facilitate insertion of the cryoprobe. Otherwise, a perineal cup biopsy was taken. After filling the bladder with air, the probe, coated with a liquid silicone lubricant, was inserted. Two freezes of five minutes at 160°c with a thaw between of about five minutes, just sufficient to loosen the probe, were done under general anesthesia. Ten minutes of warming after the second freeze permitted consistent insertion of the catheter. If the catheter could not be placed with ease immediately, no difficulty was encountered with insertion in the recovery room.

All patients had had orchiectomy. All had bone pain refractory to oral estrogen. The history of the patients is summarized in Table 1. Two case reports indicate the kind of patient selected and the quality of life achieved.

Case Reports

No. 1 (A.F.) 83 years old, in February 1971 developed progressive weakness of both legs, urinary and rectal incontinence. A sclerotic lesion in the 4th thoracic vertebrae was related to his carcinoma of the prostate proven by punch biopsy of the gland. His serum acid phosphatase was elevated at 1.9 Bodansky units.

Orchiectomy and stilbesterol 5 mg/day were instituted in early July 1971. By September his acid phosphatase was normal, but his weight had declined from 98 to 93 pounds. A constant pain in the region of T4 permitted him to sit in a chair for only half-hour periods. Walking was nearly impossible.

"Double-freeze" cryotherapy was performed on January 27, 1972. Because he said his back pain was improved, "double-freeze" therapy was again done on February 24th. Cup biopsy this time did not reveal carcinoma.

Because of his striking relief from back pain after the second cryotherapy, bilateral cataract extraction was done to permit him to feed himself. His weight rose to 103 pounds without signs of edema. He was now willing and able to walk 15 yards and to sit in a chair for two hours without protest. He was discharged to a nursing home in June 1972, four months after his second cryotherapy and one year after his admission.

No. 2 (C.M.) 69 years old had a retropubic prostatectomy in August 1968, which showed extensive carcinoma of the prostate. He was then thought to have evidence of disseminated osseous metastases on the basis of diffusely increased uptake on Strontium 85 bone scan and an elevated bone marrow acid phosphatase level of 2.3 Bodansky units (Nl. 1.1). In November of 1968, orchiectomy was done, but it did not relieve his back pain. Nine days after his first cryotherapy (a single continuous 10 minute freeze) in January 1969, his pain had disappeared. He had two additional freezes in the following two months. Estrogen therapy was not given because of congestive heart failure.

In May 1971, 29 months after cryotherapy, his bone scan did not show diffuse increased uptake as it had prior to treatment. He is still free of bone pain three years after cryotherapy. His complications were impassible stricture and incontinence for which he wears a suprapubic tube.

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TABLE 1

Patient	Bilateral Orchiectomy	Hormones	Cryotherapy	*Clinical Course of 6 Patients with Carcinoma of the Prostate Treated with Cryotherapy*	Pain
R.J.	1968	Estrogen 1968-72	1/72	(Before) (After) Acid P'ase 27 10 Bod. Units 72 lbs. 92 lbs. Died ca. 4/72	Improved
A.F.	6/1971	Estrogen 6/71-6/72	1/72 2/72	Acid P'ase—Normal 93 lbs. 103 lbs. Died 7/72 sepsis	Absent
C.M.	8/1968	Estrogen 8/68-7/69	1/69 2/69 3/69	Acid P'ase—Normal Body Weight—Not Available Alive and Well	Absent
J.T.	1967	Estrogen 1967-71	12/71	Acid P'ase—Not Available Body Weight—Not Available Died 3/72—Cause Unknown	Absent
W.B.	3/1969	Estrogen 3/69-6/71	1/72 1/72	(Before) (After) Acid P'ase 5.2 Acid P'ase .52 Body Weight—Not Available Died 6/72 ca.	Improved
P.L.	4/71	Estrogen 4/71-3/73	3/12/73	Acid P'ase—Normal Body Weight—No Change Died C.V.A. 3/21/73	No Change

Results

As summarized in Table 1, 5 of 6 patients showed subjective decrease in pain by their own report. Substantial weight gain was demonstrated in 2 and a fall in the serum acid phosphatase in 2. Often oral narcotics could be substituted for intramuscular injection, or the pain disappeared entirely (C.M. and J.T.). The improvement in bone pain was not transient and so permitted discharge to chronic care facilities in all cases. The loss of pain lasted from 3 months (R.J.) to 3 years (C.M.).

There were no complications except for an impassable urethral stricture in C.M. which dated from a time when it was thought that a lower placement of the probe would improve its effectiveness. This and three sequential freezes are no longer done.

The kind of injury to the tumor produced by the freeze may be seen in Photo No. 1.

Discussion

The clinical series does not give direct evidence that tumor immunity is operating in the patients after cryotherapy to alleviate their pain. The suggestion is only indirect. The rapidity of the response, namely within 24 hours, virtually excludes cellular immunity. With regard to humoral immunity, Ablin has shown that alpha-2 globulin decreased significantly in four patients whose osseous metastases regressed[5] after cryotherapy. It seems possible that the margins of the treated (See Photo 1) tumor could absorb "blocking factors" present in the alpha-2 globulin fraction and thus free competent immunocytes to attack the tumor in bone.

Another observation in support of tumor immunity is that a second freeze, as in the cases of C.M. and A.F., after an interval of 2 weeks frequently led to greater improvement of bone pain than the first. Schulman has shown an amnestic response to a second freeze of the rabbit coagulating gland.[6] In man, the second freeze appears to act similarly as a "booster."

Whatever the mechanism of its action, cryotherapy for palliation appears to offer advantages over radiotherapy or chemotherapy with, for example, mithramycin. Carlton, et al, found that only 20 of 40 patients had relief of obstruction after external radiotherapy.[6] Whereas, Flock, et al, reported good control of obstruction in 11 patients at the price of one bladder neck contracture[3] after cryotherapy via a perineal approach. Radiotherapy with P^{32} after stimulation with parathormone improved 15/15 with bone pain treated by Tone and Finkelstein.[7] However, their impressive results were achieved with an expensive isotope and twice weekly visits for seven weeks. Chemotherapy with mithramycin was proved effective in the relief of bone pain,[8] but its duration of action was far shorter than that of cryotherapy.

In brief, cryotherapy, because its definitive effect on local disease brings with it an unexplained palliation of pain from osseous metastases, appears to offer significant advantages over present day chemotherapy and radiotherapy for the palliation of carcinoma of the prostate metastatic to bone. Its lack of complications appears to justify its use in general hospitals before referral to specialized centers for radiotherapy or chemotherapy.

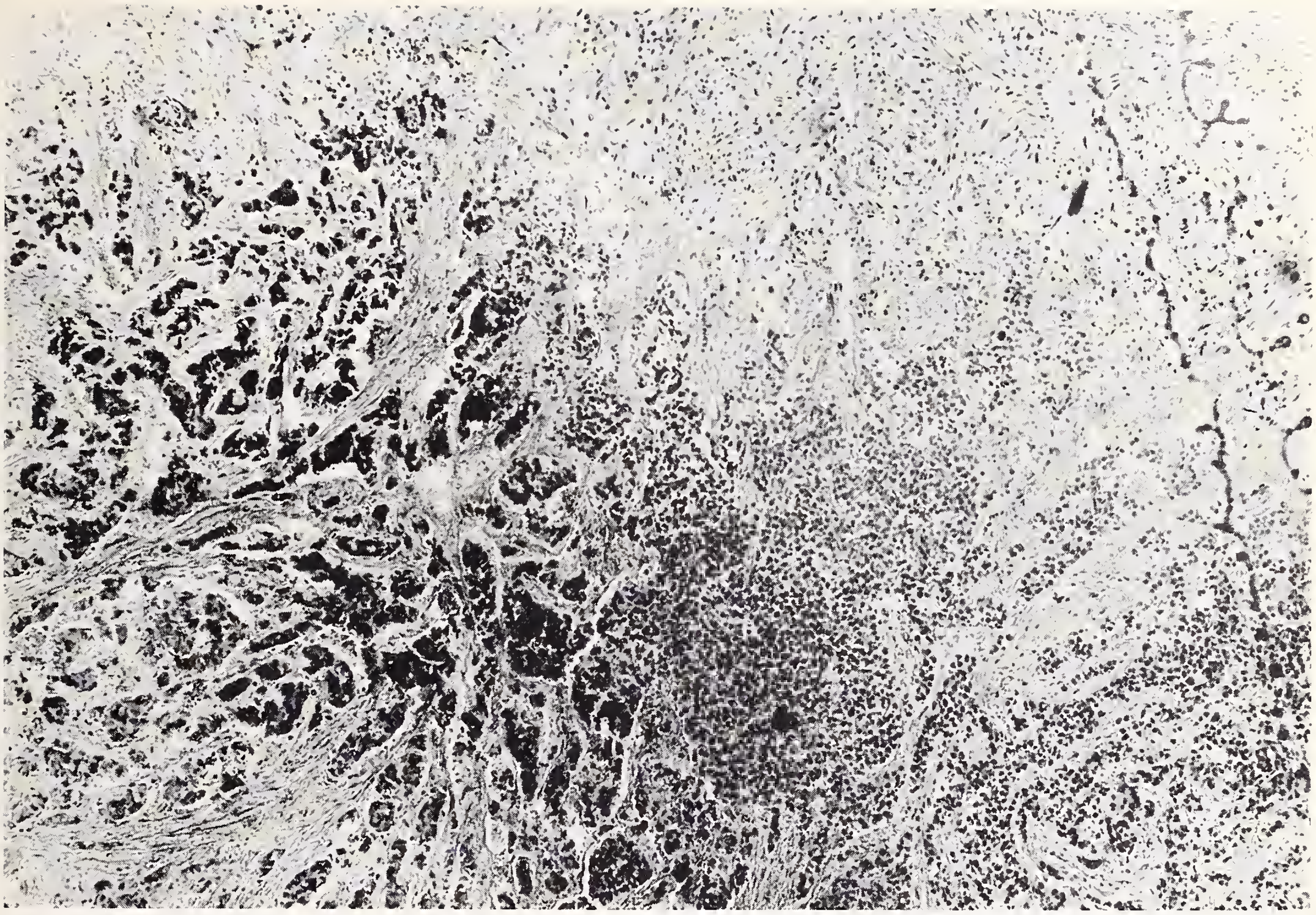

Figure 1

The margin between frozen (right) and unfrozen (left) carcinoma of the prostate 16 hours after cryotherapy. Note the abundant inflammatory exudate invading the area of injury. Could 'blocking factor' be absorbed here?

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Prescribing Fluoride Supplements to Reduce Dental Caries

Gilbert LeVine Mellion, D.D.S., F.I.C.D.
and
Ruth Berman Mellion, B.A., M.S.

The daily administration of individualized dietary supplements of sodium fluoride may be desirable for young children living in rural areas or in other locations where community fluoridation programs are not feasible. However, such administration must be consistent and continuous over long periods of time if substantial benefit is to be anticipated. Strong motivation and a clear realization of the need for careful regulation of the daily intake is required on the part of the parent.

Since dietary fluoride provides its greatest benefit during the period of tooth development, one may assume that the child should receive adequate fluoride from infancy until at least twelve to fourteen years of age. By this age, maturation of the crowns of all teeth but the third-molars should be completed.

A professional decision between the use of dietary fluoride or topical application of fluoride will depend in part upon the age of the child. Prescribing supplements of dietary fluorides may be the method of choice for the very young child, whereas topical fluoride application may be preferable for the older child whose permanent teeth are near complete calcification.

The Council of Dental Therapeutics of the American Dental Association strongly advises against the indiscriminate distribution or casual prescription of supplements of dietary fluoride.

The first step that should be taken before prescribing a dietary fluoride for a child is to have the child's principal drinking water source tested to determine its natural fluoride content. Based on the results of this analysis adjustments in prescribed dosages may be made. The Council on Dental Therapeutics has included the following table on adjusted allowances for children over three years of age, in its 1973-74 Edition of *Accepted Dental Therapeutics:*

Water Fluoride	*Adjusted Allowance*	
	Sodium fluoride	*Provides fluoride ion*
ppm	*mg. per day*	*mg. per day*
0.0	2.2	1.0
0.2	1.8	0.8
0.4	1.3	0.6
0.6	0.9	0.4

For children between two and three years of age the allowances are reduced by one-half. For children under two years of age, no specific daily allowance is suggested and instead it is recommended that water containing 1ppm fluoride be prepared with fluoride tablets or drops, and that this water be used for the child's drinking water and for the preparation of his food or formula. One 2.2 mg. tablet of sodium fluroide completely dissolved in one quart of drinking water will provide fluoridated water that may be used for infants.

Sodium fluoride tablets may be employed with the least difficulty in localities where the drinking water is substantially without fluoride. The following prescription illustrates such use for a child of three or older:

℞ Sodium fluoride tablets 2.2 mg.
Dispense 100
Sig. One tablet each day in ½ glass of water or fruit juice.
Caution: Store out of reach of children.

For the child between two and three years of age, specify either ½ tablet each day or 1 tablet every other day.

Prescriptions of fluoride *solutions* may be used more conveniently in localities where the drinking water contains inadequate amounts of fluoride. It is suggested that the use of prescribed supplements be limited to those children whose drinking water contains a concentration of fluoride ion no higher than 0.7 parts per million. The following prescription is illustrative of their uses:

℞ Sodium fluoride 0.26 Gm.
Distilled water, to make 60 ml.
Dispense in plastic dropper bottle that delivers 20 drops for each ml.
Sig. Use ______ drops each day in ½ glass water or fruit juice.

DR. GILBERT LeVINE MELLION is in private dental practice in Rocky Hill and is a past Chairman of the Connecticut Nutrition Council. He has represented the State Dental Association on the Nutrition Council for 23 years and served on the Advisory Committee on Nutrition, Connecticut State Medical Society. He is also Chairman of the Connecticut Joint Dental-Pharmaceutical Committee.

MRS. RUTH BERMAN MELLION is a nutritionist and a member of the Connecticut Nutrition Council. She has lectured and written articles with Dr. Mellion on the relationship of nutrition to dentistry.

Each drop of this preparation will provide 0.1 mg. of fluoride ion and the appropriate number of drops (8, 6, or 4) is specified on the label directions according to the table of adjusted allowances.

Vitamins and sodium fluoride have been combined in a number of products marketed as dietary supplements for infants and children. These products are frequently prescribed by pediatricians. The fixed proportion of ingredients in the combination makes it more difficult to adjust appropriately the amount of fluoride prescribed in areas where the drinking water contains substantial but inadequate levels of fluoride. For these reasons, the Council on Dental Therapeutics of the A.D.A. has accepted brands of sodium fluoride as dietary supplements, but has not accepted combinations with vitamins.

Although we know how the daily allowances should be varied depending on natural fluoride content of drinking water, in the United States we are offered only limited maneuverability to put this information into practice. To my knowledge, only tablets or lozenges containing 2.2 mg. sodium fluoride (1 mg. fluoride ion) are manufactured and sold in the United States. Thus, with solid forms of fluoride supplements, little latitude is provided for altering dosages.

In the United States one may use the previously indicated prescribed sodium fluoride solution calibrated to 20 drops for each ml. with each drop providing 0.1 mg. of fluoride ion, or one may resort to fluoride liquids which are produced by several manufacturers. These preparations are formulated so that either 4 or 8 drops contain 1 mg. of fluoride ion. Thus, one may adjust dosages fairly easily.

Recommendations

1. Before prescribing a dietary fluoride supplement for a child, it is necessary to have the child's principal drinking water source tested to determine its natural fluoride content.
2. Based on the results of the water analysis, adjustments in prescribed fluoride dosages must be made. The Council on Dental Therapeutics of the American Dental Association has developed a table of adjusted allowances which has been included in this article.
3. Before prescribing dietary fluoride, be sure the parents or guardian are strongly motivated and fully realize the need for careful regulation of the daily intake.

The information presented in this article is based on material in the 1973-74 (35th edition) of *Accepted Dental Therapeutics* published by the Council on Dental Therapeutics of the American Dental Association, and on a personal communication from Herschel S. Horowitz, D.D.S., Chief, Community Program Section, Caries Prevention & Research Branch, National Institute of Dental Research, Bethesda, Maryland.

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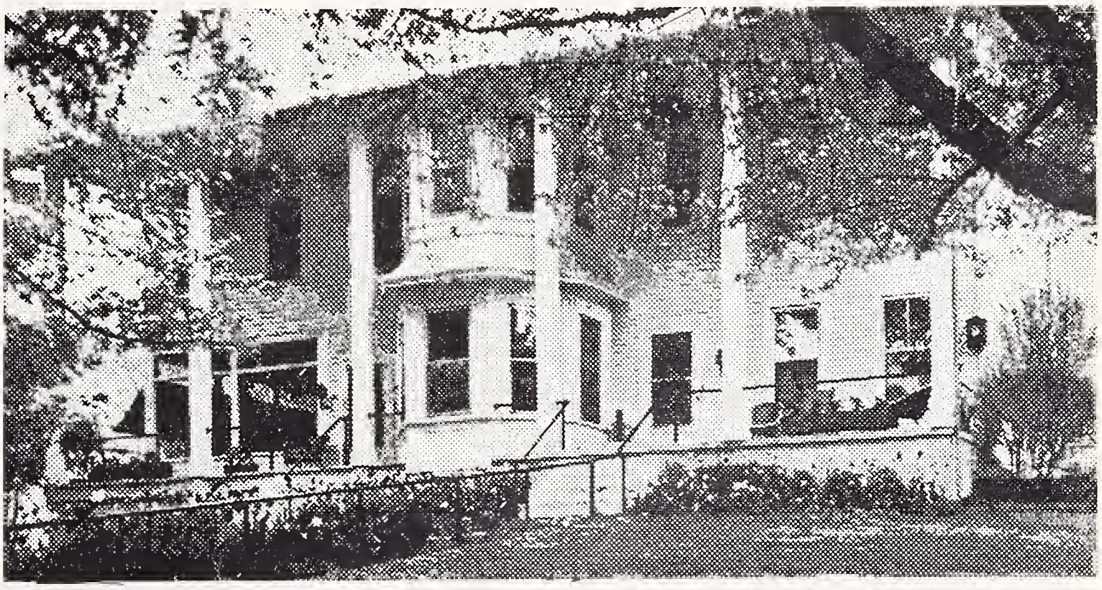
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Repeated “Rapid Resolution” of Segmental Defect on Perfusion Lung Scan

Savita Puri, M.D., and Richard P. Spencer, M.D., Ph.D.

While defects on perfusion lung scans are often due to pulmonary emboli, a variety of other causes may be responsible. It is recognized that regional alveolar hypoxia can cause decreased perfusion in the corresponding area of the lung[1] (and this is likely the basis for abnormal perfusion lung scans during asthmatic attacks). At the far extreme, occlusion of a major bronchial division can lead to a “bloodless lung” on that side.[2] Intermediate stages have not been well documented. We present here a case with 2 episodes of decreased perfusion to the same pulmonary segment. Rapid clearance of the defect probably indicates hypoxia as its basis.

Case Report

A 33 year old man was seen because of shortness of breath, diaphoresis, and left sided chest pain which was nonpleuritic. There had been no cough, expectoration or fever. Examination of the chest was negative except for a soft systolic murmur heard along the sternal border on the left, without radiation. A lung scan (2 mCi of 99m Tc-MAA) showed a perfusion defect in the left lower lobe (likely the posterior basal segment).[3] Immediately after this, the prior record was made available, and showed that he had been seen 2 years prior to the present admission because of chest pain. A lung scan at that time was interpreted as positive, while a repeat study 4 days later (after heparin treatment) was normal. A review of that lung scan showed that the defect was identical to the one seen on the present study. Because of this, the lung scan was repeated 16 hours later and was reported as normal (Figures 1 and 2).

Discussion

We are presented with 2 interesting facts. First, a segmental defect on a perfusion lung scan was not present when the study was repeated 16 hours later. Second, the perfusion defect was identical to that seen in the patient 2 years earlier. The defect at that time also resolved, although the follow-up scan was not obtained until 4 days later. This repeated “rapid resolution” of a segmental defect appears to be most readily explained on the basis of local hypoxia. As to possible mechanisms, we can hypothesize a local but readily cleared obstruction, such as a ball valve effect or resulting from an anatomic variant making that region of the bronchial tree more susceptible to mucous plugging or to obstruction by aspirated material. Repeated chest X-rays in this patient have been normal, and the arterial oxygen saturation has been 96%. All of these findings make a picture that does not fit the classical description of pulmonary embolization, and hence must turn our attention to other explanations

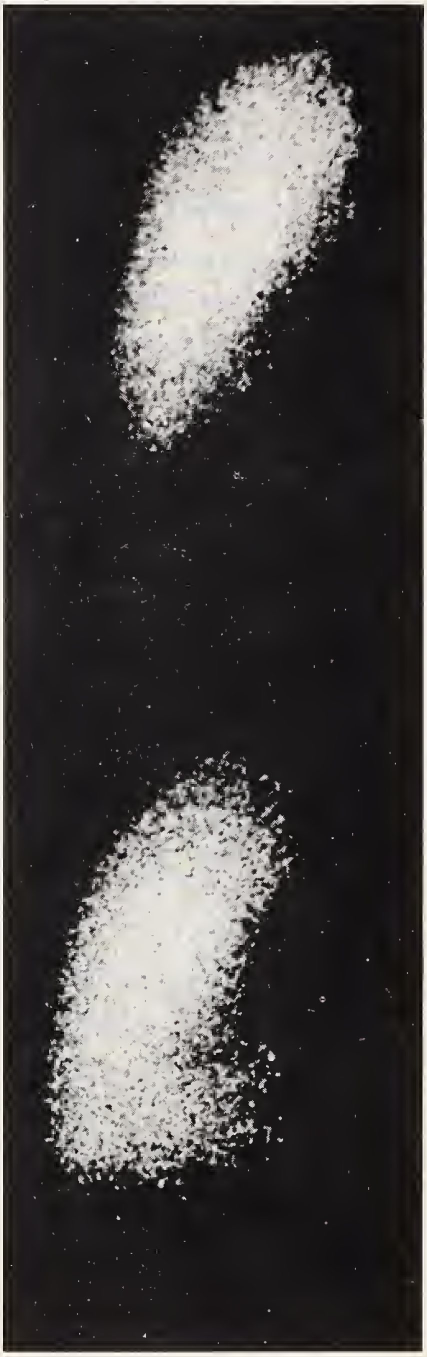

Figure 1

Posterior scintiscans of the left lung. The top view is the original study, while the bottom view is the repeat examination performed 16 hours later.

DR. SAVITA PURI, NIH Fellow in Nuclear Medicine, Yale University School of Medicine. DR. RICHARD P. SPENCER, Professor and Chairman, Department Nuclear Medicine, University of Connecticut Medical School.

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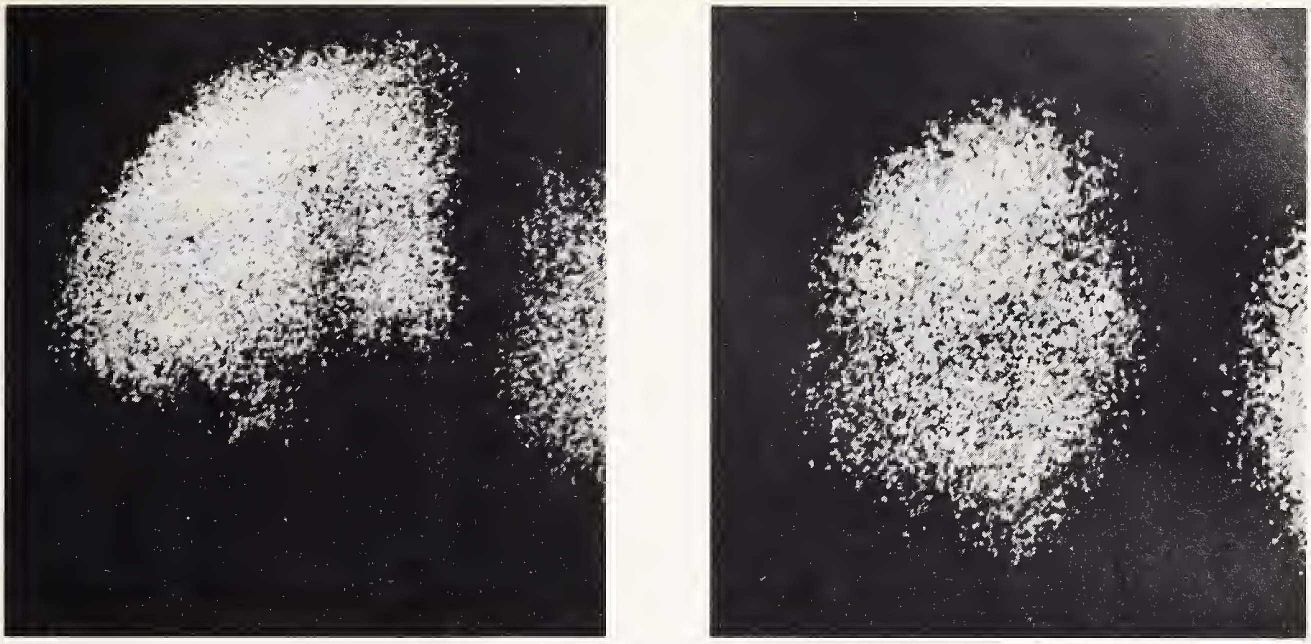

Figure 2

Posterior oblique scintiphotos of the left lung. Left: original study. Right: repeat examination, 16 hours later.

for the rapidly resolving defect. Even more pertinently, this case raises questions as to how soon a lung scan should be repeated after an initially positive study.

Summary

A lung scan in a 33 year old man revealed a segmental perfusion defect. A repeat scan 16 hours later showed the defect to be absent. The patient had a lung scan 2 years prior to the present sequence, and that also had the same defect (with resolution on a repeat study). Local hypoxia was pointed out as a probable explanation for the findings.

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Gabriel A. Ingenito, M.D. Memorial Scholarship Fund

A scholarship fund has been established at the University of Connecticut Medical School by friends of the late Dr. Gabriel A. Ingenito of New Haven.

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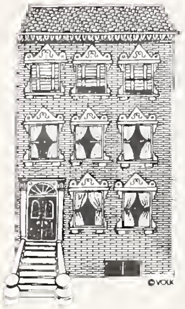
Dr. Ingenito was a University of Connecticut graduate in 1940 and had served as a member of its alumni groups. He was also a graduate of the University of Maryland Medical School and served his residency at Grace-New Haven Hospital. Dr. Ingenito practiced obstetrics and gynecology in New Haven for twenty-five years.

During World War II, he served as a captain in the U.S. Army Medical Corps. He was past president of the New Haven Obstetrics and Gynecology Society and was an assistant clinical professor or obstetrics and gynecology at the Yale Medical School.



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The President's Page

Sooner or later the medical profession will have to face the problem of unionism within its own ranks. Most of us still look upon the idea with a certain amount of horror, but slowly the advocates are growing in number.

Most of us fear unionism for two main reasons: 1. the effect it would have on our public image, and 2. most of us would be unwilling to strike if it meant not delivering needed care to our patients.

The answer of the advocates is that it is about time that physicians started to fight for their own rights in spite of the misimpressions of the public and that one may strike the system rather than the patient. One medical staff of a hospital has already done this with success. There was a difference of opinion between the board of trustees of a hospital and its medical staff. As a last resort the medical staff told the board of trustees that if it did not give in to the staff on this point, the staff would continue to care for the patients in the hospital and would write orders on the chart *but* that they would write nothing else on the chart, no history, no physical, no progress notes, no discharge summary. The board of trustees gave in.

I do not want to give anyone the impression that I am for unionizing the medical profession at this moment. The profession is not ready for it; nor have our relations with the government at this point reached the stage where such a move is inevitable. But if the present trend of governmental emasculation of the medical profession continues on its present course, such a point may be reached in the not too distant future.

We are under threat now of having our fees in their entirety fixed by government, fixed in a way that the Secretary of HEW feels is reasonable. Our experience in Connecticut particularly with the Medicaid program shows up the looseness of the term "reasonable," for certainly the fees that are considered to be reasonable by the Welfare Department are not considered to be reasonable by most practicing physicians. Until recently we were being discriminated against by the Phase IV Economics control program.

How much of this discrimination should we expect our membership to put up with before we move into the collective bargaining phase of unionism. Foundations for medical care already are moving into collective bargaining positions.

The government gives lip service to the idea that we hold most sacred, that quality of medical care outweighs in importance the cost of medical care. There are a good many of us who put our tongues in our cheeks when we hear this and wonder if this is really true. If indeed it should turn out in fact to be the opposite and that cost actually is more important than quality of medical care, then we would see the quality of medical care cut down because of the government's refusal to pay for it. This has happened in England and other countries. Then truly we would have to be in a unified position in defense of the rights of our patients, and this probably is even more important than defending ourselves.

But we must remember that when we take collective action, we give up the right of individual action to a great extent, and we commit ourselves to the action of the group through our leaders. Are we ready to give up these individual privileges yet? I don't think so, but it seems to me that if we were given the choice of giving up our privileges either to government or to our peers, we would choose our peers.

We must not forget the fates of the medical profession in Canada, England, Sweden, Russia and other countries. We must not fall into the trap of deluding ourselves that "it can't happen here."

Let me repeat; I am not urging unionism now. I hope it can be avoided. I am merely pointing out that if the government takeover trend continues on its present course, we are on a collision course with the problem of forming a union within our own ranks.

James H. Root, Jr., M.D.
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Connecticut Medicine

Editorials

The Pediatrician of the Future

Is pediatrics a dying specialty? I think not, but it is certainly a legitimate query in these times of questioning and re-evaluation. Consumer concerns and legislative levers are at work. No longer can a young person go into medicine with a completely free choice of what he wants to be and where he wants to go, as when many of us started.

In these days of the struggle and re-birth of person-to-person relationships and child advocacy the pediatrician will be phased-in more meaningfully in the delivery of primary care, the major medical problem of the moment. Family practitioners and internists will be partners in this, and the roles of "para" and ancillary personnel will need sharper delineation. By primary care one means: medicine within the personal health system rather than the public one, first contact medicine, integrational and longitudinal responsibility for the patient, and (consumer concept) immediacy and availability. Primary care is a *function,* not a discipline or a body of knowledge, though the Carer may have one of several basic disciplines from which she (he) started. The goal of the American Academy of Pediatrics is the attainment by all children of their full potential for physical, emotional, and social health. In these multi-messaged times the child and parent need an advocate and counselor for this. In a problem-oriented approach, the problems are: lack of personnel and definition of roles to go with the goals; fragmentation, transientism, the emergency room care crisis, doctors needing reasonable time off; inequality of care (quality for all depends on equality for each); costs; do it yourselfness; continuing education for physicians, further education of others; fuzziness in long-range planning; congruency between public and physician goals; the uncanny ability of bureaucracy to de-personalize; PSRO (costs, quality, confidentiality); the specific matters of nutrition, accident prevention, integration of the handicapped, and health education of children themselves.

There is a role for the pediatrician in the solution of each of these problems in the next quarter century. The solo practitioner will probably be phased out, except as an individual (with his own patients) within a group. The multi- or single-discipline group (with around-the-clock office coverage?); the health team with the pediatrician as leader-quarterback; the pediatrician as sub-specialist, specialist-consultant, and hospital based intensive care specialist; the pediatrician-in-community as aid in problem solving—all appear to be credible, viable postures. Democracy implies pluralism of process and approach. The pediatrician of the future may well be a child generalist rather than a child specialist! Dialog between him, the internist, and the family practitioner is "a must." The pediatrician's future as advocate, insurer of quality, and participant in the delivery of primary care seems assured. His further role with his in-depth background, training, and education, should be to help the other deliverers of primary care in their efforts to give the best to families and children. From whatever basic orientation the care stems there then can be partnership in a coalition for delivery of this primary care.

Merritt B. Low, M.D.

Vice President and President-Elect, American Academy of Pediatrics; Alternate Delegate to AMA and Chairman, Section on Pediatrics.

A Time for Commitment

Common to all leaders of organized medicine is the growing frustration of the poor "Internal P.R." or communication between the leadership and the "Rank and File." All of us delegates with the responsibilities of leadership from time to time feel the prods of our member critics and all too often the critics do so from a base of ignorance, irascibility, and hasty conclusions rather than thoughtful judgment. Perhaps this is better than another, more malignant frustration—the total silence of those represented, who appear either apathetic or fatalistic. Those of us who have been figureheads rarely receive carefully thought-out criticism.

Ours is not the only group not to be interested in its own leadership and seemingly not the least interested in our objectives, roles, accomplishments or even our representations to the media. It is distressing, however, to feel that our membership is deaf and blind to our statements. It is depressing to know that our voluminous statements, publications, letters, meetings, conferences, councils, committees, fora, press releases and statements are so often completely ignored. It is probable that these very words, though no clarion call to arms, will make not the least ripple in our all too shallow pool of exchange. Not only is it frustrating to feel that you are shouting into the empty barrel but the voluminous reams of information and education disbursed by state, county and local spokesmen is expensive.

Were these times of inaction and social stagnation, we could afford wryly to accept the waste of time, material and money. But we are afloat in a sea of constantly moving currents of socioeconomic change that threatens the forms of our practices and the very ways our daily lives are to be organized. It is not a new thought that we physicians must bestir ourselves to in some way become involved in the changes in the delivery of health care and the economic bases thereof.

Few of us deny that medical care is a political football and a great concern to the citizenry as well. Apathy on the part of our membership is a serious concern. Isn't it apparent to our members that we who speak for them must truly be representative of all and have a constant flow of ideas forth and back? Isn't it apparent that we must at least read and digest our own reportings? Isn't it of prime importance for us to receive a broad based support at meetings, and isn't it necessary that our committee structure receive the attendance and support it needs? Isn't it necessary for us to get infusion of new blood into our leadership, which can only be done with men who are involved in our issues and answers.

Become aware. Become evident. Become active. Become a contributor to the course medicine is to take in the days to come or collectively we will inherit rightfully what our apathy and callousness will spawn.

Isadore H. Friedberg, M.D.

President, Hartford County
Medical Association

On Writing the Synopsis-Abstract

It is one of the oddities of medical rhetoric that the shortest part of the scientific communication should so often give evidence of having been the most difficult to write. Yet, by following only three or four simple guidelines, it should be possible for even the neophyte writer to turn out a synopsis-abstract that is coherent, unified, and emphatic.

Before enumerating these principles, let us consider first what the synopsis-abstract is. Although any of several terms, such as "abridgement," "conspectus," "epitome," or "summary" may be used to describe condensation of a longer work, The Journal has hybridized two, "synopsis" and "abstract." as more nearly expressing the qualities of this condensation than would either term used alone. Thus, "abstract" applies to a summary of the main points of the article, while "synopsis" implies a skeletal or general view of the whole with the added notion of suitability for rapid examination by the reader. The synopsis-abstract is more than an abridgement of the article, which is merely a compression or reduction in length, and less than an epitome, which although brief, has independent value apart from the article it summarizes. In meaning, it is probably closest to "conspectus," literally "to get sight of," except that the latter applies to larger and more detailed works than are published by The Journal. Thus, a synopsis-abstract covers the main points of an article in such a fashion that the reader may quickly obtain a general view of what is to come in the article. It has no independent value, i.e., although the synopsis-abstract contains no information that is not also in the article, it is not a substitute for the article. It indicates to the reader only that he may or may not be interested in pursuing the topic by reading the full article. It is an indication of content, but not the content itself.

As such, we may now suggest certain guidelines, which if they are thoughtfully applied, will be an assist to the writer in composition and, ultimately, to the reader in comprehension. Thus, the synopsis-abstract may be easily written if the author will but ask himself four questions, the first three of them essential and the fourth optional: What was the problem? How did I go about solving it? What did I find? What did I learn? Or stated another way, the outline for the synopsis-abstract can be put into four words: problem, method, results, and conclusions. If the body of the article itself has been clearly written, one sentence about each of these four topics will suffice more often than not. In fact, the application of this method to the composition of the synopsis-abstract is often a cross-check of the quality of the report and even of the work, it being next to impossible to write a good synopsis-abstract for a poorly written article. Finally, do not tantalize the reader with such unnutritious statements as, "A case of blank is described and the results are discussed." Rather, answer each of the four questions with *facts* drawn from the article.

Of course, the system does not apply in all cases. Some are special and must be handled in a special manner that may tax the resources of even the best writer. Most often, however, this simple system does work, resulting in a snappy, short, coherent abstract of less than a half dozen sentences.

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M. Therese Southgate, M.D.
Senior Editor of *JAMA*

Evaluation and Management of Insomnia

Insomnia is the most prevalent of all primary sleep disturbances which the physician is called upon to manage. Recent studies in sleep research laboratories have contributed greatly to our understanding of this disorder. It has been found that over 80 percent of insomniac patients have significant psychopathology as evidenced by one or more major Minnesota Multiphasic Personality Inventory (MMPI) scales in the pathological range. Specific MMPI scales which have been found most frequently abnormal are those for depression, sociopathy, obsessive-compulsive features and schizophrenic trends. Insomniac patients, however, seldom view their difficulties in psychological terms. They are not often referred for psychiatric care and seek such care only rarely.

Although many drugs are initially effective in inducing or maintaining sleep, tolerance frequently develops within two weeks. Flurazepam (Dalmane®) seems to be the drug of choice since such tolerance does not appear to develop. In cases where hypnotic drugs have become ineffective, the drug should be withdrawn extremely gradually (at the rate of one therapeutic dose every five or six days) to minimize rapid eye movement (REM) rebound, and the patient should be warned that increased dreaming and even nightmares may occur. Drug therapy alone is usually sufficient in cases of mild insomnia or insomnia secondary to situational disturbances. More severe or chronic insomnia usually requires both psychotherapy and drug therapy.

John Geyman, M.D.

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Hemophilus Vaginitis—A Venereal Disease

Hemophilus vaginalis has been estimated to be the causative agent in 6 to 52 percent of vaginitis cases, and incidence of this condition seems to be increasing. Diagnosis requires (1) a high index of suspicion, (2) evidence of excess bacteria in a wet smear and (3) vaginal epithelial cells that look semi-opaque with a Desi® stain or Gram stain, which are referred to as "clue cells." Small Gram-negative bacilli associated with epithelial cells, rather than with leukocytes are noted. Oral contraceptives and intra-uterine devices do not influence the incidence of Hemophilus vaginitis. Sulfa vaginal creams and suppositories used for three weeks result in a 50 percent cure of this problem. However, the author has found that a course of ampicillin 50 mg four times daily for five days has been a much more effective therapeutic agent. Men who have been infected with Hemophilus have also been successfully treated with this method.

Benson McGann, M.D.

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Letters To The Editor

Letters to the Editor are welcomed and will be published, if found suitable, as space permits. Like other material submitted for publication, they must be typewritten *double spaced* (including references), must not exceed 1½ pages in length and will be subject to editing and possible abridgment.

MEDICAL FOUNDATIONS

To the Editor: At the present time a great flurry of interest has developed in the concept of medical foundations. They are purported to be entities embodying the best of both worlds in the health care delivery field by providing comprehensive medical care on a prepaid basis, while at the same time preserving the traditional, time-honored, fee-for-service system, so dearly beloved by most physicians in private practice. The actual mechanism of organization and action of medical foundations is somewhat complex and it's easy to overlook the dimensions of the forest as one grapples with the numerous trees.

It's not unreasonable to insist that any system of prepaid medical care justify its existence by providing care of a superior quality, at lower aggregate cost, and better distributed than the system it seeks to supplant. From the standpoint of the consumer, a medical foundation is an undeniable form of capitation medicine and suffers thereby from the inherent weakness of all such schemes, namely, unworkable overutilization of the facilities provided, particularly at the level of outpatient primary care. Unfortunately, this overutilization of facilities invariably results in higher aggregate medical costs for the insured group as well as a lower quality of care provided. It is a questionable solace to be assured that in an effort to forestall and control the inevitable overutilization, the mechanism of a foundation provides for intensive peer review of all procedures and charges, adherence to a rigid fee schedule and acceptance of discounted fees in the event of foundation insolvency.

One has to note that such a self-imposed plan of physician organization would diminish our freedom as doctors and citizens more stringently than anything effected to date by any governmental body or agency. In fact, if physicians so give notice that they are willing to give up their individual rights and are content to be comprehensively regimented, does this not provide a magnificent prototype for a government takeover? Furthermore, one has to speculate on the likelihood that medical foundations while nominally non-profit will be recognized, legally, as organized, de facto, for the profit of physicians and thereby, as vendors of health insurance, subject to the control of the state insurance commissioner.

The case for medical foundations would be stronger if the need for such was more demonstrably pressing. The proponents of state medicine endlessly dwell on the skyrocketting cost of physicians' fees to the point where one is convinced that an actual crisis exists. Department of Commerce statistics reveal, however, that in any given year, Americans spend three times as much on tobacco and alcohol as on private physician's fees, twice as much on bank charges, three times as much on attorney's fees, five times as much on travel and recreation and seven times as much on automobiles. Obviously this is not the picture of a society staggering under a burden of outsized doctor bills and hardly demonstrates the need for physicians to turn their world upside down and tie themselves in knots in a vain effort to control costs. This is particularly significant at this point in the evolution of our society when we are in the midst of the worst inflation the country has ever experienced and every physician in private practice needs immediate flexibility in his schedule of fees. The last thing a practicing physician needs at this time is to have his fees set by a complicated, cumbersome, possibly strife-torn organization, whose very size and nature may suggest a combination acting against the best interests of consumers and inviting, thereby, control by a government regulatory body.

The medical foundation concept is an interesting one and worthy of careful study. It is not a facile answer, however, to the problems medicine faces from the direction of government intervention. It involves physicians yielding up personal sovereignty to a degree that heretofore has been totally unacceptable and fiercely resisted. As such, one wonders if the cure suggested is not worse than the disease presented, insofar as the controls imposed by a foundation quite possibly go beyond anything proposed by government, which, after all, has to take into consideration the rights of individuals, including doctors, as defined in the Constitution. Could medical foundations be organized medicine's Trojan horse?

John J. McGarry, M.D.

Darien, CT.

THE JOURNAL

To the Editor: I would like to take this opportunity to express to you my personal appreciation of the very fine job which you have performed as the Editor of *Connecticut Medicine*. This is now one of the best Journals of any of the State Medical Societies.

With all good wishes.

John Donnelly, M.D.
Psychiatrist-in-Chief
The Institute of Living

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Reflections From The Dean's Office

Robert U. Massey, M.D.

One of the declared goals of the University of Connecticut School of Medicine faculty is "to provide for continuing education." Furthermore this is to be carried out "in cooperation with health practitioners."

Both state societies and specialty societies have been considering requirements for continuing education as a basis for reregistration or recertification. During the past decade, the number of continuing education courses in medical schools has increased by 93 percent, and the number of physicians registering for such courses has increased by 172 percent, probably exceeding 225,000 in 1973-1974.[1]

These data suggest growing recognition by practitioners and medical educators of the importance of a continuing renewal of knowledge and skills. Admittedly, they say nothing about the quality, content or effectiveness of the many efforts to provide post-graduate education in an agreeable form. Perhaps the most important goal of undergraduate medical education, and indeed of all higher education, is to create "an intellectual environment which will attract and stimulate the best students, helping to form habits of lifetime learning." Although this is a frequently stated goal, no one is very clear about how to achieve it. "The justification of a university," Alfred North Whitehead wrote, "is that it preserves the connection between knowledge and the zest of life, by uniting the young and the old in the imaginative consideration of learning. The university imparts information, but it imparts it imaginatively.—A university which fails in this respect has no reason for existence."[2]

Hopefully the student entering medical school brings his intellect and his appetite for learning with him. Too often, we suspect, his intellect may have been dulled and his appetite deadened by years of tedious unimaginative teaching. If this continues for the professional student in medical school, any hope for a lifetime of learning may be vain, and journal reading, scientific meetings, and continuing education courses will become dry burdensome exercises, rendered even more so by some legal requirement for self-renewal. Fortunately for medical educators, much of learning in our profession takes place in the clinics and at the bedside. Here the setting may fire the imagination and the skillful instructor has an easier time of it, although even in the drama of human suffering lackluster teaching may lose the auspicious moment.

I suspect there is another element necessary for continuing renewal in the life of a physician. In addition to his intellect and his appetite for learning, he requires a high moral commitment. The ignorant or poorly prepared lawyer may lose his client's fortune; the ignorant or poorly prepared physician may cost him his life as well as his fortune. Unless the physician has a keen sense of this ethical burden, he will be at best mostly ineffective, and at worst, dangerous.

The appetite for learning, like other appetites, has a way of waxing and, more often, waning under the influence of physiologic and psychologic events which are difficult to control. It may be supplanted by other appetites, or directed to other objects, quite worthy in themselves. To sustain him as he confronts his private demons, the physician requires an especially highly developed ethical system.

Kohlberg[3] has described a hierarchy of stages of moral development which he believes can be measured, and which he suggests may be largely culturally independent. If his thesis should prove correct, we may be able to evolve better ways of selecting students for those professions where morality is a matter of public concern.

Driven by zeal for new knowledge and an ethical commitment to excellent patient care, physicians will seek out their own ways of self-renewal. Legalistic requirements for 150 hours of attendance at meetings and courses may be necessary for a few stragglers; recertification or reregistration requirements may come in due course, but only after the majority are meeting them anyway. The law tends to follow custom. To use it to compel behavior which is not already desired may be largely futile. To use it, in this instance, to remind medical schools of their obligation to the profession may be most salutary.

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ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut, School of Medicine, Farmington.

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Humanism in Human Experimentation: Some Notes of the Investigator's Fiduciary Role

Edmund D. Pellegrino, M.D.

Human experimentation; ethics of consent; investigator's fiduciary role; human values

> Today, perhaps the first and only duty of the philosopher is to defend man against himself, to defend man against that extraordinary temptation to inhumanity to which—almost always without being aware of it—so many human beings today have yielded.
>
> — Gabriel Marcel[9]

Modern medicine is painfully torn between its technologic possibilities and its traditional trusteeship of the integrity of the persons it serves. Positioned squarely between the sciences and the humanities and uniquely combining both in the lives of individuals and communities, medicine can be man's most potent instrument for enhancing his existence. Yet, in few endeavors is man so much in danger of being overshadowed by one of his creations. Can medicine somehow unite its humanistic and scientific elements and become the genius of a new humanism, in which technology serves human purpose? Or will medicine become the paradigm of a technocratic anti-humanism, in which man himself becomes an abstraction?

This tension between human concerns and technologic possibility is exquisitely adumbrated in research with human subjects. Here, the traditional mandate of the physician as helper comes increasingly into conflict with his new mandate as scientist and fact-gatherer. Can medicine remain faithful to both trusts—to be the most scientific of humanities and the most humanistic of the sciences?[13]

The reality of human experimentation forces the investigator to a conscious selection of a set of personal values. But a close inquiry into some of the central ethical issues in experimentation is essential for the practitioner, as well. The same forces of science and technology are just as profoundly transforming the nature of the everyday relationship between the physician and his patient. Indeed, the same care we employ in experiment ought to be used more often in the more mundane affairs of clinical practice.

This discussion is deliberately focused on the personal transaction between subject and investigator, rather than on normative principles. There is a real danger of succumbing to the powerful abstractions of science and research if we do not root our considerations in persons. It is easy to slip quite unknowingly into the callous and careless use of human beings to serve some attractive ideal like "advancing knowledge," or "elegant experimental design," or "benefiting mankind." Unless our consideration is embodied in a concrete human relationship and we the investigators examine our personal actions in that relationship, we risk the "extraordinary temptation to inhumanity," which the French philosopher Gabriel Marcel perceived to be one of the great evils of our times.[9]

The social control of experimentation will not preserve us from that evil. Research is a realm in which social dependence on technical expertise is inescapable. Human experimentation committees, regulations, and adults are essential, but they are also insufficient alone to guarantee the humane use of human beings. There are too many precedents in human affairs for violating the spirit of the law while observing the letter. Regulation can become a substitute for individual responsibility. It is impossible to monitor each measure introduced in the course of an investigation. The investigator may take the approval of his protocol for obtaining a "valid" consent as a license for all his later decisions in an experimental protocol. The central issues are inescapably clear; the investigator is always in a fiduciary role. His superior competence and expertise force the ultimate responsibility for their ethical usage upon him, even in a regulated system. Each investigator must, therefore, develop a personal

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DR. EDMUND D. PELLEGRINO, Chancellor of the University of Tennessee Medical Center, Professor of Medicine and Vice-President for Health Affairs, University of Tennessee Medical Units, Memphis Tennessee. He is a consultant to the Institute for the Humanities in Medicine at the University of Texas Medical Branch.

Dr. Pellegrino has been appointed to a newly created position of chairman of the board of the Yale-New Haven Medical Center, Inc. and assumed his new post this year.

Delivered in part as the Benedict Abreu Memorial Lecture, University of Texas Medical Branch, Galveston, Texas, April 27, 1973.

stance in the way he exercises his fiduciary role. The only absolute proviso is that he engage the issues consciously, put his values in order, and be prepared to alter them with experience. Not to do so limits his freedom as a man and as a physician. This is the first step in dehumanizing the investigator; the dehumanization of the patient-subject is sure to follow.

There are at least three levels of personal concern in the value matrix within which the investigator functions: the societal mandate given him, the peculiar nature of the physician-subject interrelationship, and the crucial personal responsibilities that derive from them. It is the interplay of these value sets that the investigator must engage as a person.

I. The social mandate

The physician, the patient, and the experimental subject are part of a social collectivity that stands to benefit by responsibly conducted medical research. Every new treatment or operation ultimately must be tried for the first time in humans; every advance in knowledge of prevention and understanding of disease depends ultimately upon observations in man. Insulin, liver extract, penicillin, smallpox and polio immunizations—all had to be evaluated in human beings, even after extensive animal trial. Society will not willingly give up these benefits, and so it permits medical research in humans.

Francoeur even argues for a "technological imperative," which would impel man to use his new technology in medicine, even if it is dangerous. Man, Francoeur says, must join God in "creating future generations" and should apply his knowledge, always seeking the *via media* between the dangers and the benefits of technology.[4] While the perils of an overzealous pursuit of this view are obvious, the consensus of social opinion would seem to favor some modified version of the technological imperative.

While recognizing the *de facto* necessity and reality of human experimentation, there is no explicit sanction in law for the practice. Medical practice acts do not assign experimentation explicitly to the physician. The prevailing social and legal opinion is that he does experiment only at his own risk. The pertinent citations in Professor Jay Katz's invaluable casebook on human experimentation refer only tangentially to "experimentation."[6] The courts use the term loosely—and certainly not explicitly to cover clinical investigation as it is practiced all over the world. Society clearly recognizes the value of human experimentation for all its members, but just as clearly it avoids assigning the authority for its conduct. Paradoxically, regulatory mechanisms are being developed everywhere, often under governmental sponsorship. The investigator is always in the dubious limbo of being a hero at one moment and a villain the next.

While thus indirectly sanctioning investigators, society explicitly requires that certain values essential in a democratic society also be carefully preserved—the right to life, to privacy, and to dignity; the right to consent or to refuse to participate; the right to veracity and competence on the part of the investigator; and the right of redress for any injury that results from an ill-advised or unethical experiment. It is the terrible violation of these rights by the Nazi physicians and their less horrendous abuse by some contemporary investigators that have necessitated the spate of new ethical codes and the legal and institutional regulatory mechanisms within which investigations must now be conducted.

Two important conclusions can be drawn from the inescapable conflict of values that society imposes on the investigator. Since society's mandate is a heavily conditioned one, the privilege to pursue investigations is absolutely contingent upon the investigator's willingness to accept the trust for the preservation of the integrity of the person of the subject. Society's mandate in this respect is far stronger than its mandate to do research—and far more important to its own health as a human agency.

The second conclusion is that any experiment for therapeutic purposes or to further our understanding of disease mechanisms, by its nature, imperils the personal rights of the patient or the subject. Experimentation with humans cannot be conducted in a democratic society without some invasion of fundamental human rights. What we must seek is the degree to which society and the individual will permit these rights to be invaded, and under what conditions, in order that new knowledge may be obtained for the good of the subject or his neighbors.[14]

We must take special note of the fact that the investigator does not enjoy, explicitly or implicitly, a social mandate to advance scientific knowledge as an end in itself. This is permissible in other scientific disciplines but not where another person must yield up some of his inalienable rights, even if he volunteers to do so and consents "freely." In short, our contemporary social values sanction research involving humans if there is no alternative way, if there is reasonable expectation of good for the subject or for society, if the subject participates in the decision to be part of the experiment, if the subject genuinely partakes in the decision to participate, if the study is worth doing, if it is carried out competently, and if the investigator assumes the fullness of his fiduciary role at every step. Only under these conditions will our social value system permit significant risks to well-being and to life—much as we do in space or underseas exploration, for example.

It is this highly qualified social mandate that the investigator must reflect upon and re-examine when his enthusiasm for the advance of science, his own career, or his intellectual delectation threaten to blur the sources of his privilege. The matter is uniquely important in the university setting, since that ambiance places such high value on research that its pursuit too frequently appears casual. No matter how minimal his contribution may be, each physician must realize that his fiduciary responsibility begins at the moment of his personal involvement. He has a fundamental obligation to adhere to the limitations of the social mandate, not only in his own behavior but also in his responses to the behavior of others. The investigator is party to a social contract between himself, the subject, and society. The fundamental obligation that arises therefore cannot be displaced to others, to group decision, or to "higher authority."

II. The personal transaction between subject and investigator

Let us examine this fiduciary role more closely. Granting his recognition of the heavily conditioned sanction under which he operates, the first level of the investigator's personal concern must be a full appreciation of the unequal nature of the transaction between himself and his patient or subject. The inequality will vary in magnitude, depending upon the particular confluence of such factors as the subject's education and social level, emotional stability, physical debility, or special circumstances of his life as prisoner, student, mentally retarded person, child, or the altered state of his consciousness. Moreover, if the subject is a patient, his eagerness for a new cure or a new lease on life will alter his responses profoundly. The desire to be of service to others in the cases of volunteers in nontherapeutic experiments is an equally potent modulator of the delicate personal contract between investigator and subject.

Concealed forms of coercion are many: the overadulation of the unsophisticated for science and technology, the mystique that still surrounds the physician, the patient's desire to please, or the weight of group pressures to volunteer. Overriding these is the superior technical expertise of the physician-investigator. The patient or subject is totally dependent on him for information on the utility, probability of outcome, and risks involved in the proposed procedure. The veil of technical jargon, together with the subject's dependence upon the investigator's competence and goodwill at every stage of the procedure, markedly accentuate the inequalities between them.

On the investigator's side, there are subtle but powerful forces operating to erode his fiduciary role. The investigator has chosen research using human beings as his life's work. His advancement and prestige depend upon publication of significant results. He must complete his work on a tight schedule. To compete successfully, he must be rigorous in his design, study a sufficient number of patients, and satisfy the canons of experimental elegance. The young investigator must break into the ranks of established investigators; the established investigator must maintain his hard-won prestigious position. Both are susceptible to that subtle shift of standards to which Professor S. E. Luria referred recently as "the ethics of competitive enterprise."[8]

These influences may be sublimated in apparently strenuous efforts to assist mankind. Self-deception is easy and readily rationalized. It is difficult to discern where legitimate dedication to high-quality humane research ends and the hubris peculiar to the physician-scientist begins. This intersection of personal human values with social and scientific goals is intense and crucial. No test of an investigator's humanism is more rigorous or revealing.

Yet, it is within the context of these personal pressures and the inescapable inequality of his relationship with the patient or subject that the investigator must exercise his fiduciary responsibility. Out of this nexus, valid consent must be elicited, for this is the very first and the ineluctable requirement for any degree of ethical authenticity or even of humaneness in the transaction. In a free society and even with a social mandate permitting experimentation, only the subject is free to yield some of his rights over his body and run the risks of injury or discomfort inherent in any procedures—experimental, therapeutic, or diagnostic. We must never forget that the patient and the subject do so in a situation in which they can never be wholly free or wholly informed in any absolute sense. Without the irreducible minimum of a valid consent, we would be indulging in the monumental pretension of selecting "martyrs for society," to use Pappworth's phrase.

Since consent cannot be totally free or totally informed, we are forced to speak of *valid consent* instead. A valid consent is one in which the subject, the investigator, and subsequent reviewers agree that the subject is a full partner in the decision to participate and under what conditions. Consent is neither free, informed, nor valid unless there is maximal possible opportunity for self-determination. This, in turn, requires full disclosure about the purposes of the experiment, the nature of the procedures, the dangers and discomforts they can produce, the benefits to be gained, the assurance that the subject may withdraw at any time, and information on whether the experiment is a substitute for standard treatment. When experimental design requires some concealment, the fact must be disclosed, together with the general nature of what is concealed.

The phenomenology of human consent is extraordinarily complex, even in the ordinary affairs of mankind. We cannot analyze it in detail here. But it is essential to remember that, even in ordinary affairs, to consent is always to yield up one's will—at least in part—to another, and this act confers upon the elicitor of the consent the power to limit another person's freedom. When consent occurs in the medical and research relationship, its already complex dynamics are exponentially accentuated.

The necessity of valid consent is at the heart of any consideration of humanism in experimentation. It is the most crucial arena for the exercise of the physician's fiduciary role; it reveals most clearly the texture of his motivation, his veracity, and his humanism. The execution of a proper consent form, while necessary, is no substitute for the investigator's responsibility to assure *quality* of the consent. Like other regulatory measures, it guards against gross abuses of privilege, but its authenticity rests with the investigator. It is the quality of human consent, therefore, that must be the central concern of the humane investigator, and not the punctilious filling out of consent forms, however detailed or well-intentioned. Indeed, the length and detail in a consent form may be inversely related to the quality of the subject's comprehension and consent.[3]

There are other special features of the investigator's personal relationship with the patient-subject, such as the rights to privacy, to dignified treatment, to confidentiality, to redress—all of which bear on the genuineness of the investigator's fiduciary role. But if the original consent to participate is invalid, there is no likelihood that these other human rights will be preserved with any assiduity. The spirit of the investigator's humane concerns, therefore, is best revealed in the quality of the consent he obtains.

III. Authenticity of the fiduciary role

Certain clear personal moral responsibilities derive from the two unique features of human experimentation just discussed—its limited social mandate and the inequality of the personal transactions it encompasses. There is no more stringent test of a physician's humanism than the way in which he exercises the fiduciary responsibilities thrust upon him in every detail of a humanely conducted experiment with humans. Despite external regulations, the fiduciary function must ultimately be monitored by the person of the investigator. This means that each physician willing to undertake this awesome duty must develop some catalogue of values against which he can judge the humaneness of his acts.

This is an especially onerous task in the face of the current trend to moral relativism in which every effort is expended to expunge guilt from human affairs. Yet, without some conscious ordering of values, accompanied by a sense of personal culpability for the injustices which erroneous values may impose, the fiduciary role can never be authentic. No set of legal or institutional constraints can guard against the cumulative evil that subtly evolves from small indifferences. The investigator is compelled, therefore, to scrutinize his value choices and constantly refurbish them. This demands a conscious reflection on some of the most fundamental issues of human existence—an inimical exercise to a culture infatuated with means and unused to the contemplation of ends.

The investigator, therefore, is enjoined to deal with those questions that do not have a true/false answer, the "first order" questions, the stuff of philosophy.[7] And it is precisely this mode of thinking for which his scientific training does not prepare him. It is these same questions that some philosophers, themselves overawed by science and technology, call "meaningless." Yet our philosophical propositions govern behavior and justify actions. They demand explicit cogitations, the lack of which depersonalizes the investigator and makes his actions automatic rather than human.

What are some of the dimensions of humane concern which the investigator must ponder? We can inquire here only into five of them—an incomplete list, unavoidably colored by the author's own values, but nonetheless exemplary of the kind of internal dialogue that must go on. The reader will have his own list and his own ordering of it. The only indispensable activity is that there be a list, that it be consciously examined, and that the investigator feel personally answerable for its probity and humaneness.

a) *The realm of meta-ethics*

The first and perhaps the most important and most difficult level of inquiry deals with the conceptual frame that underlies our ethical choices and values. This is the realm of meta-ethics, and it conditions each concrete decision. It is the source of the ethical norms against which we label our actions as right or wrong. Most of us move quickly to normative principles without any conscious reflection on their sources in our deepest convictions—those so identified with our conceptions of what we are, that only the more intellectually and emotionally mature can probe to these depths without profound anxiety.

Our meta-ethical axioms have profound consequences for our patients. They transcend the mere fact of "acting according to conscience." On what, and how, is that conscience formed? There is a vast difference, for example, between the absolutist who makes his "principle" the final arbiter and the situational ethicist who uses the "situation" of the act and its consequences as his guide. In the first instance, right and wrong are antitheses, philosophical contradictories with little or no ground between them. This is the stance of much of classical ethics, and it can easily make "abstractions" of men. The situational ethicist, in contradistinction, may be the victim of an accommodating relativism that can be stretched to fit any subjective presupposition he chooses. Lying, in the absolutist view, is always wrong; in the situational view, it may be the moral thing to do.

But in most of the circumstances the investigator encounters, the conflict is between two or more values, both having merit.[16] Rather than choosing between good and evil, we are forced to choose good versus good or better versus worse—for example, telling the truth as against the mandate not to harm the patient or cause him anxiety; or the relief of suffering against the mandate to preserve life; or putting one person in the presence of risk to obtain the good of many others.

We are not suggesting what conceptual mode to follow in making these decisions but only underscoring the necessity of understanding *how* we do make our decisions. To undertake this task in some reasonable fashion requires some understanding of the history of ethical theory—its origins in Aristotle and Plato, its infusion with Christian theology in Aquinas, its transformations and modulations in the thinking of Kant, Hegel, and the modern existentialists and pragmatists. The delineation of our meta-ethical assumptions is a complex and lifelong task. It involves an understanding of our entire "attitude in the fact of the human condition," as Maritain has phrased it in his critical study of the presuppositions of ethical theory.[10]

These presuppositions are themselves finally rooted in our idea of man. Explicitly or implicitly, every human subscribes to a metaphysics of man—the sum total of the presuppositions he makes about the meaning and the value of human existence and the existence or nonexistence of a transcendental order beyond man. Manifestly, it matters a great deal whether one subscribes to the views of a Marxian humanist like Schaff, who sees man's end as a happy life on earth,[17] or to those of a Christian humanist, who sees that life is fused by a spiritual element transcending man, or to those of a dozen other humanisms, each with its own spirit and values.

We must understand our own presuppositions as well as we can and then make an attempt to understand those of the patient—an even more difficult task. Yet, without some intimation of the patient's values, we cannot guard against one of the more subtle forms of inhumane behavior—the imposition of our value sets on another person who is not free to resist or, worse still, is not afforded the opportunity to express his own values. Physicians are especially susceptible to the unthinking and condescending transfer of their authority in technical matters to the realm of human values.

Knowing the configuration, therefore, of his own value choices and those of his patients is an essential for the humanist investigator. This is exquisitely the case at every stage of the process of consent, where the intersection, conflict, and harmonization of values proceed simultaneously. It is impossible to obtain a valid consent, much less one whose "quality" is that of a humane decision, without sensitivity to the issues that arise out of the meta-ethical geography of the beliefs held by subject and investigator.

b) *The ethics of good science*

But, even before we approach the use of patients, we must examine the second dimension of the fiduciary role, and that is our authenticity as scientists. Science has its own ethical base. To put a person at risk for ill-conceived scientific reasons or with bad experimental design is a serious violation of trust. Is the research question trivial? Is the experiment a duplication? Will the methods provide the answer sought? Are we personally competent in the procedures involved, or will we be learning them in the study? Is the design rigorous, the control adequate, and the information worth having? Or, on the other side, are we being overly rigorous to satisfy our esthetic sense of what constitutes "elegant experimental design?"

Anyone reviewing experimental protocols or refereeing the papers that result from them must conclude that these questions are not asked often enough. This is particularly true in drug evaluation—a form of clinical investigation too lightly entered into but most difficult of all investigations to conduct competently. Is the drug worth pursuing for human use? How much preclinical testing is enough? On whom shall we try it first? Can we justify such research when an effective treatment already exists?

These questions must be asked repeatedly before we set out on any investigation. Otherwise, the momentum generated by the research ambiance will propel us into immoral exposure of humans to risk without sufficient reason, or even uselessly, if our design leads to erroneous or inconclusive results. The ethics of science may occasionally conflict with the ethics of good patient care once an investigation is initiated, but, if adverted to beforehand, the canons of good science are additional guarantees of the morality of the experiment.

c) *The quality of consent*

Having a clear idea of our own values and how we deal with them, and having determined that we have a scientifically valid experiment, we must examine the third dimension of our fiduciary role—the quality of the consent we obtain. Earlier in this essay we defined the requirements for a valid consent. These can be fulfilled to the letter, and still the consent can lack those qualities that make it the consent of a free person.

As we are obtaining consent and after we have obtained it, we must question ourselves closely. Did we gain consent more by suavity, eloquence, or subtle duress than by frank disclosure of the information the patient needs to make a decision? Did our zeal for the experiment override the patient's fear or reservation? Did we tell the patient enough about the discomfort and the risks? Did we excuse ourselves on the specious grounds that the patient would not understand or might be made overly anxious. In a therapeutic experiment, can we really offer the patient some probability of help for his condition? Or is he merely another case we need to fill out the protocol? Having once obtained consent, do we regard it as immutable and also as a cover for new and unanticipated procedures the experiments may later require? Are we sufficiently open to the patient's doubts after he has consented, and do we allow ample opportunity for a graceful withdrawal?

We cannot overstress the significance of the quality of human consent. It is the pivotal point in the fiduciary process, the crucible of our veracity, the place in which the psychological and intellectual integrity of the subject can be most subtly and unconsciously invaded.

d) *The conduct of the experiment*

The fourth dimension of humanism in the use of humans in experimentation is the actual conduct of the experiment. Have we taken the pains to make ourselves sufficiently skilled in the techniques involved? Do we insist on doing them out of motives of pride? Have we chosen the safer or the more spectacular and fashionable methodology? Do we know when to discontinue the experiment, either because of patient discomfort, or because we have enough data even if the protocol has not been carried out to the letter, or because another investigator has already made our work redundant? Or are we thinking more of the eventual report, our survival on the academic scene, the approbation of our colleagues?

We might put the ultimate test to ourselves more often—perhaps routinely, as Lawrence Altman has suggested:[1] Are we prepared to submit to the experiment ourselves or even postpone seeking any subject's consent until we have performed the procedure on ourselves? The subject of auto-experimentation is a difficult one, which I believe will be discussed more frequently as we look more critically at our humanist responsibilities. It is difficult to ignore the example of Nobelist Werner Forssman, who first performed two of the most important cardiological techniques—catheterization and angiocardiography—upon himself.

e) *Corporate responsibility*

The fifth dimension and the last, which illustrates the sort of self-examination the investigator must practice to keep the person of the patient or subject always in his consciousness, is his acceptance of corporate responsibility for the ethical behavior of the research group. The research team, which is a commonplace today, is made up of a wide variety of people—physicians, basic scientists, nurses, students, fellows—each sharing some aspects of the protocol. Responsibility under these conditions, is easy to diffuse even when there is a leader who takes prime responsibility. For a morally respectable experiment, the fiduciary responsibility must be shared by all who participate. Each member of the team must feel responsible for violations of trust in any of the dimensions iterated above.

This may be an especially difficult duty for the student or the young physician, who is the junior member of the team. Yet, we cannot escape the conclusion that if others fail in their trust, he must speak up, object, drop out of the team, or take action to put an end to the injustice. If he does not, he easily becomes what Gabriel Marcel called the "auxiliary bureaucrat"—the assenting small man who takes orders in a vast system, excusing himself by virtue of his subordinate position. Of such were the Nazi physicians who committed their atrocities in the service of the ideologies of National Socialism and of a science divorced from value.

We have only examined a brief list of some of the questions each of us must answer as we enter the privileged and dangerous domain of human experimentation. They are derived from the personal responsibilities that flow from the social mandate that permits human experimentation and the unique characteristic of the physician's personal transaction with the patient as a subject. It is not too much to ask the investigator, at least periodically, to examine his conscience on points such as these. Each investigator conscientious about his fiduciary role will devise his own list.

The personal fiduciary role each investigator willingly assumes demands a conscious, critical, continual self-examination as the antidote to complacency and automatic behavior, which gradually lead to making an abstraction of our neighbors and which are the greatest dangers of technology. This is not to impose either paralyzing scrupulosity or a neurotic and obsessive rumination on every past or future action. Rather, what is dictated is a mature, balanced self-examination, assisted by colleagues and the patient as well, which will enable the investigator to be both scientist and humanist.

IV. Educational Implications

Perception of the growing tension between the technologic and the humane values of medicine has generated great interest in a richer humanistic education for the physician. Current patterns of pre- and post-degree medical education do not prepare the physician for the sort of cogitative self-examination suggested here. Indeed, most of his professional education is indifferent or even antithetical to these activities—particularly to philosophic reflection.

At present we rely on whatever exposure the student may have had in liberal or humanistic studies, during college to sensitize him to issues of human values. That this is insufficient has become apparent for a number of educators in and out of medicine. New programs to make the humanities an integral part of professional education are being developed widely.[15]

Katz has suggested a method for the more specific education of medical students in the legal, moral, and social issues attending the physician's role in human investigation.[5] He describes a seminar for law and medical students based in the case study method. His approach has the advantage of concreteness and immediacy, two essential attributes of any program intended to engage the medical student's interest.

Some of the levels of inquiry we have suggested will, however, require in addition a more formal exposure to the philosophical attitude of mind. Clouser has described the difficulties and the rewards of such a "mixed marriage" as might occur between medicine and philosophy.[2] The American Philosophical Society has recently recognized the significance of its interface with medicine by establishing a committee to cultivate the exchange. Certainly, the most fundamental of the questions on which the physician-investigator must take a position are in the philosophical realm. While some students might be prepared to examine issues philosophically by virtue of their college training, the majority will need explication or reinforcement of this mode during and after their medical education. We have outlined the issues in humanistic education for health professionals elsewhere, as well as the particular points of interface with philosophy.[12] [11]

Lewis Mumford has pointed out that value is integral to all human experience, and knowledge separated from value, or the idea from its embodiment in man, created the monstrosity of the atom bomb. The expanded potency and capability of medicine as applied biology and applied behavioral science in their own way can match the potency of the atom bomb. The atom bomb can annihilate man. But technology separated from value can produce something perhaps more terrifying—the denial of humanity to living men. Marcel was right to define the temptation to inhumanity as the greatest evil in our society.

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SPECIAL NOTICES

UNIVERSITY OF CONNECTICUT HEALTH CENTER ONCOLOGY LECTURE SERIES

Friday afternoon 4:00 p.m. — except note*

February 21, 1975
"ACUTE LEUKEMIA IN ADULTS"
Peter Wiernik, M.D.
Baltimore Cancer Research Center
Baltimore, Maryland

March 21, 1975
"HODGKIN'S DISEASE"
Kirby Smith, M.D.
St. Jude's Hospital
Memphis, Tennessee

April 4, 1975
"ROLE OF THE IMMUNE SYSTEM IN CANCER"
Robert Kassel, Ph.D.
Walker Laboratories
Rye, New York

April 18, 1975
"VIRUSES AND CANCER"
Sol Spiegelman, Ph.D.
Columbia University
New York, New York

April 21, 1975 (Monday)*
"RADIATION INDUCED CANCER"
Marvin Frazier, Ph.D.
Batelle—Northwest Laboratories
Richland, Washington

May 16, 1975
"PEPTIDE HORMONE RECEPTORS IN NORMAL AND NEOPLASTIC CELLS"
Jesse Roth, Ph.D.
National Institutes of Health
Bethesda, Maryland

May 30, 1975
"LEUKOCYTE KINETICS AND THE TREATMENT OF LEUKEMIA"
Bayard Clarkson, M.D.
Sloan—Kettering Institute
New York, New York

June 6, 1975
"RADIOBIOLOGICAL CONSIDERATIONS IN COMBINING RADIATION THERAPY WITH SURGERY AND CHEMOTHERAPY"
James J. Fischer, M.D.
Yale University
New Haven, Connecticut

Medical Conference Room B-3094
University of Connecticut Health Center
Farmington

Supported by: American Cancer Society
Connecticut Division, Inc.

Medical Malpractice

A California Report

This is the first report ever issued by any state legislative committee investigating malpractice—"The Select Committee on Medical Malpractice of the California Assembly, 1974."

These findings and recommendations are in preliminary form. The investigations will be continued with a final report in one year (1975). The chairman, Assemblyman Henry Waxman, has introduced a legislative package for the 1974 Assembly session. Proposals such as no-fault insurance or compulsory arbitration of all claims must await further study.

Findings

1. The number of cases in California has increased from 13.5 per 100 physicians in 1965 to more than 18 per 100 physicians today—40% increase.

2. Rates have increased more than 400% between 1968 and 1970.

3. Group insurance rates have increased more rapidly than the number of claims filed because the average closing cost of claims (verdicts and settlements) have increased from about $4,500 in northern California and $5,800 in southern California in 1969 to between $7,000 to $8,000 in the same respective areas.

4. The principal reason is that more patients are suing today.

5. More patients are suing because: (a) The relationship is less personal, due to urbanization, specialization of providers, use of medical insurance programs to finance medical care, and malpractice litigation itself. (b) Legal rights explosion. (c) The media causes greater expectation from medicine and informs patients about legal avenues to sue. (d) More plaintiffs' lawyers are becoming expert. (e) Doctrinal changes by the judiciary have widened the scope to facilitate favorable judgments.

6. Some physicians are now practicing defensive medicine, resulting in both positive and negative aspects.

7. The malpractice insurance market is highly unstable. Carriers may be priced outside the market.

8. There are a great number of variables in setting medical malpractice rates—frequency of high verdicts and settlements, relatively small size of the market, time lapse when policies are underwritten and claims are first filed, difficulty in predicting the trend and frequency of claims (Ed. inflation!).

9. The major effect as perceived by the physician is damage to his reputation and goodwill.

10. There is little evidence that a large number of non-meritorious suits have been filed. Medical malpractice is becoming a highly specialized field of litigation, and becoming a specialty within the legal profession.

11. Claims against hospitals are rising faster than claims against physicians. The trend will continue.

12. More patients are obtaining greater compensation from medical malpractice.

13. Patients who suffer malpractice where damages do not warrant verdicts under $10,000 are unable to obtain legal counsel to litigate because it is not worth lawyers' time and effort to accept small cases, even though malpractice may be obvious.

14. The increased premiums are passed on to consumers in higher health cost.

15. Only about 16-25% of the premium dollar goes to patients.

16. Malpractice litigation has led to some improved medical practice and quality of care.

17. The Medical Practice Act in California is deficient in standards for disciplining physicians who have committed medical malpractice.

18. Volunteer peer reviews have improved the quality, but by themselves are insufficient to insure good health care.

19. Voluntary arbitration is becoming more common.

20. A primary conceptual difficulty in establishing no-fault medical malpractice insurance system is determining what such a system would cost.

Legislative Recommendations by the Committee: Legislation is required to complement the rapid changes taking place in medical malpractice by judicial action if reforms are to be rational and far-reaching rather than just piecemeal and ineffective. So the Committee divided its recommendations into those requiring immediate action and those for further study for the final report in 1975.

Recommendations for Immediate: (1) Publicity: The ad damnum clause, or prayer for, specific monetary damages should be eliminated. It gives a distorted inflated view of the value of malpractice cases. The original demands were on the average about 53 times higher than final actual awards. The accused physician gets a lot of publicity in the beginning, but he doesn't get later comparable counter-

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Abstracted by Editor from *Medical Malpractice*, Assembly Select Committee, Preliminary Report, 1974.

vailing publicity. (2) Malpractice Insurance for Members of Hospital Staffs: Hospitals should be permitted to require this. In California, the Rosner case stated the law in California—that hospitals cannot do this, absent a statute. (3) Notice of Intent to File Suit: Written notice of intent to file such suits should be provided a potential defendant within a specific time before the running of the statute. (4) Alteration of Medical Records: Modification, alteration, or destruction of medical records to mislead or misinform the patient should be made a crime. (5) Qualified Privileges: Physicians should have qualified immunity to exchange information with the respect to discipline and qualifications of physician. (6) Insurance Reporting: Companies should be required to report relevant data to the Department of Insurance about claims. (7) Grounds for Discipline on the Medical Practice Act. The State should be enabled to discipline physicians found to be "incompetent." (8) Expediting Disciplinary Proceedings: An accused physician now may through a judicial stay delay an administrative order revoking or suspending his right to practice. In such cases proceedings should be expedited. (9) Screening Mechanism (mandatory): Screening panels or independent panels of experts could, on request of either party, screen cases to eliminate nuisance cases. (10) Collateral Source Rule: Presently a double recovery of insurance is permitted. So a patient is paid not only by his medical insurance but also by malpractice resulting in an increased burden on tax payers. (11) Statute of Limitations Applied to Minors: At present minors need not bring suit during infancy. The Committee recommends that this rule of law be eliminated. (12) Arbitration of Small Claims: Establish arbitration for claims under $10,000. (13) Reorganization of the State Board of Medical Examiners: Disciplinary functions are now bad. Split the functions of licensing and discipline. Also all general hospitals should have an ombudsman for patients. (14) Access to Medical Records: A patient's attorney should have a clear legal right to get the information in a patient's chart.

Recommendations for Further Study: (1) Contingency Plan in Case of Absence of Private Carriers: The State should adopt a contingency plan to provide malpractice insurance to all physicians in case it becomes unavailable by private insurance carriers. (2) Informed Consent: The standard imposed by Cobbs v. Grant [California Case Law] is important, but it should be clarified in the form of a statute which would establish the law for consent, superseding any judge-made definition as now done. (3) Specialization of Attorneys: Attorneys in the field of malpractice should be trained as specialists, with standards established by legislation for attorneys who bring malpractice action. (4) Punitive Damages: The law must be clarified about this. (5) Contingency Fees: There should be a sliding scale for contingency fees for lawyers established by legislation, as was recently established by New Jersey (by its Supreme Court). (6) Loan Guarantees on Malpractice Insurance: The state should provide loan guarantees to physicians requiring help because of high insurance premiums. (7) Licensure of Medical Specialists: Study of this requirement should be made. It may be desirable. (8) Reexamination of Practitioners: The requirement of periodic relicensure should be considered. (9) Corporate Responsibility for Hospitals: Should there be a statute to enact into positive law the duty on hospitals to determine whether their medical staff is competent? (10) Reversionary Trusts: In making awards, there should be revisions providing for reversionary trusts for longevity awards, instead of determining damages on life expectancy basis. (11) Alternative Methods of Financing Litigation: At present contingency fee is the only method available by which plaintiffs can finance litigation. On the other hand, the Committee believes there are serious limitations in the method. The contingency fee idea should be reconsidered. (12) Arbitration: Should compulsory arbitration be required in medical malpractice suits? There should be further study in this field. (13) Question of No-Fault Insurance: Further study should be done on this before any legislative action is taken.

This selective Committee was formed in April 1973, in response to the increasing number and amount of awards. "In 1969 there were 3; in 1970, 5; in 1971, 9; in 1972, 13; and in 1973, 24—all over $300,000. The estimate of the average closing costs has become between $7,000 and $8,000. In February 1973 there was one settlement of $4,025,000 to a 13 year old boy. Last November, one for $2,000,000; another for $1,300,000. Northern California had the largest malpractice settlements ever—one for $2,000,000 and the other for $1,300,000. The Committee's initial concern was to investigate and fully explain why malpractice claims had increased so dramatically. It did send a questionnaire to 2,000 professionals seeking information. Public hearings were held.

There are at least 5 major reasons that more people are suing: (1) a changing doctor-patient relationship; (2) the legal rights explosion; (3) the impact of the media; (4) increased proficiency of trial lawyers; and (5) changing legal doctrines.

Several among these principles are (1) Locality Rule: Originally a physician had the duty to possess and exercise only that degree of care and skill customarily possessed and exercised by other practitioners in the same or similar locality. In California, however, this standard has been much broadened increasing the malpractice problem for physicians.

Res Ipsa Loquitur: With the greater availability of expert medical testimony this doctrine has lost much of its importance in California.

Informed Consent: The recent case of Cobbs is now the law in California. It permits the jury to decide whether consent has been "informed" rather than it be established by the use of expert medical testimony.

The Nork Case. This nationally publicized case stated what may be a far-reaching doctrine as to corporate responsibilities of the hospital. He stated: "The hospital has a duty to protect its patients from malpractice by members of its medical staff when it knows or should have known that malpractice was likely to be committed upon them. The hospital had no actual knowledge of Dr. Nork's propensity to commit malpractice, but it was negligent in not knowing. It was negligent in not knowing that it did not have a system of acquiring knowledge." The decision is moot by a settlement, but if followed, could extend the liability of hospitals for malpractice.

Malpractice Insurance: Those physicians who have had a record of malpractice suits may soon find themselves either paying exorbitant rates to high risk carriers or simply unable to obtain insurance. "Is the increase in premiums reasonable? Bluntly, are the companies accentuating the malpractice problem through a desire to reap excessive profit from writing malpractice insurance?" . . . "Unfortunately, the answer is a difficult one." The method of arriving at a premium is complicated. For example, in 1971 American Mutual had 15 claims (1.7% of all) accounting for 50% of all idemnity payments.

Nuisance Suits: More trial lawyers are getting into the field because of its lucrative potential combined with possible loss of work from the threat of no-fault insurance.

Contingency Fee: In most other countries it is either prohibited or rarely used. It is used in virtually all auto and products liability, and other types of personal injury actions. Only the very rich are able to afford an attorney on a different basis. A defendant insurance company would take every step to prolong litigation and avoid settlement if the average plaintiff had to pay for his own case. Eventually, he could no longer finance it.

Peer Review Committees are fearful of legal repercussions for statements made by the members of these committees about the conduct of practitioners. Clear legislative qualified immunity is preferable for such committees.

Alternate Methods of Resolving Medical Malpractice Claims: (1) arbitration. Governed by the Uniform Arbitration Act. (2) no-fault insurance—to be studied further. (3) creation of an administrative agency to resolve malpractice claims—to be studied . . . These are being studied and will be reported on in 1975.

The Connecticut Confidentiality Statutes

Sherry E. Marcy, M.P.H.

In 1961 and again in 1969 the Connecticut General Assembly enacted model statutes dealing with privileged communication and confidentiality between psychiatrists and their patients. While many patients and general physicians assume that their communications are privileged and/or confidential, this is not so according to law. Connecticut was one of the first states to grant privilege to psychiatrists' patients in 1961. This protection was extended to confidentaility of communications between psychiatrists and their patients in 1969. Physicians who do not practice psychiatry are not covered by the current statute. This paper will review the arguments for and against privileged communications and confidentiality which were reflected in the General Assembly debates resulting in the enactment of the 1961 and 1969 statutes.

Communications are "privileged" when they cannot be required to be revealed in a court of law; communications between husband and wife and between lawyer and client are privileged. Communications are "confidential" when the party to whom the communications are made is required to be discreet, but " . . . the mere fact that a communication was made in express confidence, or in the implied confidence of a confidential relation, does not create privilege."[1] Nor does the assurance of privilege imply assurance of confidentiality, though there may be separate legal sanctions supporting the confidentiality of a relationship.

The 1961 law made communications from a patient to his psychiatrist privileged in a court of law, with certain carefully described exceptions. The 1969 law expanded the 1961 law to include not only privilege in courts of law but also confidentiality in all situations by providing for the recovery of damages if the patient's confidentiality were violated, and to cover not only face to face communications but also all written records.[2]

I will explore whether or not disclosure for the public interest, as evidence in a court of law, outweighs any detrimental effects such disclosure might have on the general psychiatrist-patient relationship. Further, I will review reasons for and against sanctioning confidential communications, including written records, between patients and psychiatrists. Finally, I will attempt to assess what the impact of the statutes (if any) has been.

The Arguments For and Against Privilege

Professor Wigmore puts forth a general principle of all privileged communications.[3] He names four fundamental conditions which must be fulfilled before privilege ought to be established:

"1. The communications must originate in a *confidence* that they will not be disclosed;
2. This element of *confidentiality must be essential* to the full and satisfactory maintenance of the relation between the parties;
3. The *relation* must be one which in the opinion of the community ought to be sedulously *fostered*; and
4. The *injury* that would inure to the relation by the disclosure of the communications must be *greater than the benefit* thereby gained for the correct disposal of litigation."

Hayt and Hayt observe, "Under the common law, no such doctrine of privileged or confidential communication existed. In England, from whence our common law emanates, there is no privilege between physician and patient."[4] In the pro and con arguments which follow, Wigmore's four points, particularly the last point, are those which are argued by both sides in the General Assembly. Many of the arguments are relevant to *physician*-patient communications as distinct from *psychiatrist*-patient communications. It was feared by lawyers, though, that the latter privilege, if allowed by the General Assembly, would be extended too easily to physicians in general.

The psychiatrists' point of view is argued very articulately in a report published by the Group for the Advancement of Psychiatry (GAP) in 1960.[5] Essentially, the GAP report maintains that psychiatrist-patient communications meet Wigmore's four points. Privilege is essential to psychiatric treatment and the social value which effective psychiatric treatment has for the community outweighs the potential loss of evidence in courts of law, according to the report. The fact that the privilege belongs to the patient and not the physician is reaffirmed. That the privilege is needed at this time, it is argued, is owing to the great increase in the use of psychiatric testimony, particularly in divorce, custody and personal injury cases. Very often the psychiatrist finds himself in the position of being forced to give damaging evidence against his own patient. Moreover, the specialized language of psychiatry is often misunderstood by juries. A psychiatrist deals with

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communications of fantasy as well as of truth, but the distinction is often difficult for laymen to appreciate. Without a statute granting privilege, psychiatrists may keep abridged records, which may adversely affect the quality of care. For all these reasons, the report concludes, privilege should be granted.

The GAP report discusses many difficult questions raised by the creation of this privilege. Psychiatric examinations are done more and more frequently for purposes other than treatment, for example by the police, courts and other law agencies, and by employers. What should be the legal status of these communications? Commitment proceedings pose another gray area. Might the privilege sometimes obstruct good treatment? When the psychiatrist also acts as the agent of an institution (such as a mental hospital, a prison or an employer), how would privilege affect this dual loyalty on the part of the psychiatrist?

The GAP report puts forth a "model statute:" "The confidential relationship and communication between psychiatrist and patient shall be placed on the same basis as regards privilege, as provided by law between attorney and client." This model does not even attempt to deal with some of the complications raised in the report. The GAP report did set the stage, however, for legislative action and sparked the interest of some of the members of the Committee on Psychiatry and Law to get some such statute passed.

Chafee[6] and Wigmore both present strong cases against the granting of privilege. Most of their arguments are aimed at physician-patient communications, though these arguments are germane to psychiatrists. Again, many of the arguments center around whether or not this privilege meets Wigmore's four preconditions. First, they argue that there is no precedent in common law. Since centuries of experience never gave rise to this protection in common law, there must be no deterrent to seeking treatment in the absence of such privilege.

Second, a law only granting privilege would actually act to protect physicians, rather than patients. They ask, why protect the physician from having to give evidence when the patient is not given any protection should the physician breach confidentiality. It is a far more common occurrence that a psychiatrist talk shop in a social situation or publish confidential clinical material than that he be required to reveal confidences in a court of law. There is a strong implication in both Chafee and Wigmore that physicians are seeking prestige for their profession in seeking this privilege.

Third, they argue that the analogy drawn to lawyer-client privilege (see the GAP report model statute) does not hold. The fact notwithstanding that the grounds for lawyer-client privilege are tenuous, lawyers and their clients are always involved in judicial process. Physicians' clients, on the other hand, are not generally concerned about litigation, and therefore this sort of concern is not active as a deterrent to seeking help. As Wigmore says, "the functions of the two professions being entirely distinct, the moral effect upon them of the absence of the privilege is different."[7]

Fourth, privilege is equated with the suppression of useful truth. If the privilege belongs to the patient, then he may select which physician he wishes to testify and exclude others, for example in a personal injury suit. Further, this privilege might allow certain patients to perjure themselves. Rather, all evidence should be presented, and juries ought to be trusted to understand difficult testimony and to discount testimony based on its source. Similarly judges may be trusted to decide whether or not sensitive testimony is actually needed for the just disposition of a case.

Finally, assuming such a privilege were enacted there are many difficult questions in defining its scope. How is a physician (or psychiatrist) defined? Are his agents to be included in the privilege? What constitutes the relationship? If a patient is unconscious in an emergency situation, has he entered into a privileged relationship? If a psychiatrist acts as the agent of an institution, do all members of the institution stand in a privileged relationship to the patient? What constitutes a communication? Should privilege be extended to include records, and if so would public health records be included? Are all letters, for example, or other documents concerning the patient covered? If not, how is the patient to distinguish what is covered from what is not? Questions of scope, it is argued, are too difficult to solve for particular cases by a general statute. Therefore, any statute should be written very broadly with its application to be at the discretion of the court.

In summary, both Chafee and Wigmore argue that the public interest of avoidance of miscarriages of justice outweighs any possible damage to the physician (or psychiatrist)-patient relationship. The crux of the argument on both sides is over Wigmore's fourth condition, namely that "the injury that would inure to the relation by the disclosure of the communications must be greater than the benefit thereby gained for the correct disposal of litigation." There is no essential disagreement that the psychiatrist-patient relationship meets the other three conditions.

The lawyers in the General Assembly worried about the effect of granting this privilege on particular kinds of cases. Psychiatric testimony is sometimes key to the just outcome of cases involving double indemnity insurance, contesting of a will or the recovery of compensation for personal injury and mental anguish. Psychiatrists, on the other hand, felt that their testimony in divorce and custody cases was often destructive to their patients and others and did not serve the cause of justice.[8]

The 1961 statute resolved these conflicting interests. It carefully defined "patient" and "psychiatrist." A patient is "a person who communicates with, or is treated by, a psychiatrist in diagnosis or treatment;" a psychiatrist is "a person licensed to practice medicine who devotes a substantial portion of his time to the practice of psychiatry, or a person reasonably believed by the patient to be so qualified."[9] Certain exceptions to the privilege were delineated, namely in the case of commitment proceedings, when the court has ordered a psychiatric examination, or "in a civil proceeding in which the patient introduces his mental condition as an element of his claim or defense, or, after the patient's death, when said condition is introduced . . . "[10] and the judge agrees to the disclosures. Finally, in testimony before the legislative committee, Mr. Abraham Goldstein of the Yale Law School, speaking for the bill, asserted that this privilege ought not to be extended to physicians other than psychiatrists: "I think that we ought to protect only those relationships which society determines are essential to the maintenance of certain important public policy, here an effective mental health program in Connecticut."[11]

Arguments For and Against Protection of Confidentiality

The major controversy over the 1969 statute took place within the ranks of the psychiatric community. The State Board and Department of Mental Health, the State Psychiatric Association and the Connecticut Mental Health Association spoke for the need for gathering data for research and planning on the one hand, while the New Haven Civil Liberties Union and the New Haven Area Mental Health Association supported patients' right to confidentiality. Because the issues concerned the way in which psychiatrists conducted themselves vis à vis their patients, and no other groups were integrally involved (as were lawyers in the 1961 controversy), it was reasonable that the fight would be in this arena.[12] All involved agreed that everyone wanted a statute: the data gatherers for protection against claims of unethical procedure and the patients' rights people to protect patients against the growing network of information systems.

Two conflicting bills were originally introduced in the General Assembly. The first concerned itself primarily with privacy of patients in all situations, not just in court. It set up legal sanctions, allowing suits for civil damages, against the breach of confidentiality. It also provided for confidentiality of all information, whether spoken, written or computerized, about the patient. Recognizing the legitimacy of research, the bill detailed procedures allowing research and planning information to be gathered and used, though these procedures were cumbersome. The procedures named a state-level committee which was to review all research needing uncoded information, that is, information with identifying marks intact. All in all, the bill was heavily weighted in favor of patients' privacy interests.

The second bill dealt mainly with how much leeway the State Department of Mental Health had in gathering and using "confidential" information. The provisions were quite broad and were aimed at making the handling of information easy for the department.[13] This bill also would have completely rescinded the 1961 statute.

Chafee and Wigmore both strongly criticized the granting of privilege to physicians (and psychiatrists) partly because patients were not protected against breaches of confidentiality although the latter was thought to be a far more common problem. The GAP report, however, pointed out certain problems which might arise should legal sanctions supporting confidentiality be included in the law. How could the psychiatrist relate to the patient's family, especially if the patient were psychotic, homicidal or suicidal? Psychiatrists sometimes resort to bill collection agencies. If this became a breach of confidentiality, is this fair to the psychiatrist whose patient will not pay? Finally, and most important politically, would confidentiality mean that research and centralized planning could not be done? What protections could be extended to the patient and at the same time allow information to be collected for research and planning purposes?

During the controversy over the two different bills, this last issue became the central one. The final compromise, which became law, provides that the Connecticut State Commissioner of Mental Health may collect names of patients on a state-wide basis, but for all other research or planning activities, patient data must be stripped of identifying information before leaving the treatment facility or psychiatrist's files. All other provisions of the "patients' rights" bill remain intact though certain procedures are simplified.

The 1969 law also allows the psychiatrist to reveal only the name, address and fee to a bill collection agency. Also, information may be transmitted to other persons or facilities engaged in the treatment of a patient without his consent provided that he is informed of this transmittal. Finally, all provisions and exceptions of the 1961 law regarding privilege are retained.

Impact of the Statutes

Both the 1961 and the 1969 statutes broke new ground by writing into law explicit provisions for privilege and confidentiality of communications between psychiatrists and their patients. The 1961 statute is one of the proposed federal rules of evidence which the Supreme Court follows for its standards.[14] The 1961 statute was the first to define the scope of privilege by beginning with a list of carefully worked out definitions, and by delineating certain exceptions. Its impact on the actions of psychiatrists is difficult to measure, but it does allow psychiatrists to resist pressures to testify, so that most of the time any possibility of this is ruled out before a case gets to court.

Lansing Crane, a lawyer working for the Drug Dependency Unit of the Connecticut Mental Health Center, researched the confidentiality statutes in connection with his job.[15] He finds the 1969 statute most interesting and important. It is the only state statute which goes this far in explicitly protecting against not only a threat to the psychiatrist-patient relationship but also a threat to the patients' right to privacy by providing legal sanctions against breach of confidentiality in all contexts. The statute also includes agents of psychiatrists, thus protecting against breaches of confidentiality by institutions. Furthermore, all information, even that computerized,[16] is covered by the statute. In sum, the statute is very strong in protecting patients' interests.

On the other hand, many are not aware of the law. Specifically, patients, mental health professionals in private practice (as opposed to those working within institutions) and agents of the law are less apt to know of it. Partly because of this and also because the law is so strongly protective of patients' rights, Mr. Crane felt that the statute is not always obeyed. Some psychiatrists follow a selective pattern of conformity; they may alternatively ignore the statute or apply undue pressure for consent. This together with the relative powerlessness of patients, especially institutionalized patients, can sometimes lead to lapses. The National Commission on Marihuana and Drug Abuse, speaking in another context, has pointed out the problem:

> " . . . [T]he law does not exist in a social vacuum, and legal alternatives can be evaluated only with reference to the values and policies which they are designed to implement and the social context in which they are designed to operate."[17]

The statutes themselves, though, stand as excellent examples of well written laws which serve the public interest while protecting the individual.

REFERENCES

1. Wigmore, John Henry, *Evidence in Trials at Common Law*, Volume 8, revised by John T. McNaughton, Little Brown & Co., Boston, 1961, p. 528.
2. The two statutes were enacted as Connecticut General Statute 52-146a.
3. Wigmore, *op. cit.*, p. 807.
4. Hayt, Emanuel and Hayt, Jonathan, *Legal Aspects of Medical Records*, Physicians' Record Co., Berwyn, Illinois, 1964, p. 74.
5. *Confidentiality and Privileged Communication in the Practice of Psychiatry*, formulated by the Committee on Psychiatry and Law, Group for the Advancement of Psychiatry, Report No. 45, New York, 1960.
6. Chafee, Zechariah, Jr., "Privileged Communications: Is Justice Served or Obstructed by Closing the Doctor's Mouth on the Witness Stand?", *Yale Law Journal*, 52: 586, 1943.
7. Wigmore, *op. cit.*, p. 813.
8. Senator Frances Finney, who shepherded the bill through the Judiciary Committee, confirmed this as did Dr. Jay Katz and Mr. Morris Tyler (personal communications).
9. These definitions are quoted from the current Connecticut General Statute 52-146a (1969) which differs only slightly from the 1961 version.
10. Connecticut General Statute 52-146a (1961).
11. Proceedings of the Judiciary Committee, hearings for the 1961 bill. Mr. Goldstein and Dr. Jay Katz wrote a paper describing the history and implications of psychiatrist-patient privilege especially in regard to the Connecticut statute: "Psychiatrist-Patient Privilege: the GAP Proposal and the Connecticut Statute", *Connecticut Bar Journal*, 36: 175-189, 1962. I also spoke with Mr. Goldstein by phone.
12. The controversy occurred off the record. Accounts of the passage of the bill stress the cooperation of all concerned. See Bursten, Ben, M.D., "The Connecticut Confidentiality Statute," *Connecticut Medicine*, February, 1971.
13. The GAP report comments: "State regulations which require notification to the Department of Mental Health or corresponding agency of the names of patients, especially those committing themselves voluntarily to a hospital and bearing the cost of their hospitalization and treatment, present a problem in the matter of confidentiality . . . Similar problems exist where patients attend psychiatric outpatient clinics and wards in general hospitals. The reasons given for this notification are often specious and have no validity in practice." The Commissioner's office needed the names of patients as a check against counting the same person twice if that person were to be admitted to two different facilities in the state. In practice a person's name changes (from Robert Jones to Bob L. Jones for example) or two people have the same name making such a check inaccurate. For planning purposes a count of admissions may be sufficient. Dr. Jules Coleman, at the time a member of the State Board of Mental Health, pointed out that since the State Department of Mental Health's plans were not implemented ordinarily, the accuracy of the department's statistics was an academic issue anyway.
14. These rules of evidence may be a form of legislation since state cases appealed to the Supreme Court will have these standards applied to them (personal communication from Mr. Goldstein).
15. Mr. Crane was recommended to me by Mr. Goldstein. This analysis of the impact of the 1969 statute is largely based on a lengthy conversation with Mr. Crane.
16. This statute is unique in that it explicitly provides for computer technology. However, the cost of converting computerized data as the statute directs may lead to lapses in following the law.
17. *Marihuana, a Signal of Misunderstanding*, National Commission on Marihuana and Drug Abuse, New American Library, Inc. 1972, p. 32.

The Doctors Versus the Lawyers

Allen D. Allen

Judge Wolfe was having trouble getting to sleep. In the morning he would have to rule on whether the district attorney had enough evidence against Leroy Brown to bind him over for trial. That trial, if it took place, involved substantial risks for Leroy, whose rights the judge had sworn to protect. Less altruistically, the judge would, in a large sense, be on trial himself. If he bound Leroy over, and the trial judge subsequently dismissed the case on the grounds that the state did not have enough evidence to make a prima facie case, it would not look good on Judge Wolfe's record. He thought about calling his physician for a sedative.

Dr. Anderson, except for his income, still maintained the life-style of an intern. It was well after midnight and he was not yet decided on whether to do the angiogram on Mrs. Winston in the morning. Did the clinical evidence justify the risk? After all, his primary responsibility was to keep Mrs. Winston alive. And the premium on his malpractice insurance had already taught him to practice defensive medicine. He wondered why he hadn't gone to law school instead of becoming a physician. By now he might have been a judge and at least could be getting a reasonable amount of sleep.

Judge. Physician. Both weigh complex evidence in order to arrive at decisions which can have a profound effect on the lives of others and on their own careers. But do they go about it in the same way? On the surface it would seem that they do not. Certainly the physician often has trouble understanding the way in which the court conducts its business, just as the attorney is often baffled by the methods of the physician. Yet, in a paper published in 1972,[1] I demonstrated that the scientific method and the judicial method are alike in many respects. Surprisingly, the differences that do exist between them stem in part from the fact that the courts are more "scientific" than scientists when it comes to skepticism and objectivity. This comparison—reported previously in *Psychology Today*[2] and *The American Bar Association Journal*[3]—is summarized here in terms of medical versus judicial fact-finding.

To begin with, it is worth noting again that both the physician and the court are in the business of evaluating evidence. Generally, they go about it in essentially the same way. For example, CORROBORATION is important in both instances. The testimony of one witness becomes more important if it is supported by the testimony of a second witness or some physical evidence such as a thumbprint. Similarly, the tubercular-like shadow on a chest plate becomes more ominous in the presence of a positive sputum culture. In neither case, however, is evidence examined in a vacuum. Rather, the information that comes before a court or a physician is often evaluated under certain pre-existing assumptions. These assumptions can be divided into two classes which I call NEGOTIABLE ASSUMPTIONS and NON-NEGOTIABLE ASSUMPTIONS.

A non-negotiable assumption is an assumption which is not altered by the presentation of evidence. In law this is referred to as a "conclusive presumption" and is fairly rare. An example is the conclusive presumption that a child born in wedlock is the issue of its mother's husband. The child's blood type might indicate quite clearly that this is not the case, but the court will not even listen to such testimony. The physician, trained to deal with physical facts, might find this frustrating, even irrational. However, it is not that the court is irrational or arbitrary, it is that the law is concerned with fostering certain public policies. As a result, a court must sometimes reach a conclusion that is not really true and that the court does not really believe. (Indeed, judges frequently find things to be different than they actually are in order to circumvent the literal dictates of the legislature and deal with a special case on its own merits. This is just a game, but a necessary one since the codified laws are rarely adequate for dealing fairly and reasonably with every case that can arise.) Medical science too has its non-negotiable assumptions. Of course, in medicine the non-negotiable assumption is non-neogitable precisely because its physical truth has been firmly established. The germ theory of infectious disease is one example of a medical assumption that can not be negotiated. In other words, one can not talk today's physician out of the idea that the etiology of an infection has to do with microscopic organisms rather than, say, evil spirits. So, both the court and the physician operate under some non-negotiable assumptions. The distinction

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(algorithm: a rule of procedure for solving a mathematical problem).

is that the court's have to do with fostering public policy and are not necessarily true nor believed to be true.

The negotiable assumption is an initial assumption which *can* be changed by evidence to the contrary. It too is used by both court and physician, but on a much wider basis than the non-negotiable assumption. The court uses negotiable assumptions —called "rebuttable presumptions"—to place the burden of proof on those making some particular argument. The presumption of innocence in criminal trials is an example with which almost everyone is familiar. In medicine, the negotiable assumption arises from statistical inference and, as such, forms the very basis of modern pharmacology. In particular, the physician must begin with the initial assumption that any drug will have its usual effects (both therapeutic and untoward) on any of his or her patients, barring some a *priori* information to the contrary. (Otherwise, the physician would have no basis for ever prescribing any medication.) On the other hand, the prescribing physician must be willing to abandon this assumption if a specific patient develops paradoxial or idiosyncratic reactions.

Closely related to the negotiable assumptions underlying the pharmacological prescription is the legal principle of *DE MINIMIS NON CURAT LEX*. This principle states that the law is not concerned with trivial discrepancies between what one promised to do and what one actually did. Similarly, if a drug is an effective sedative in 98% of the population, then the fact that it is ineffective in 2% of the population does not prevent the medical community from thinking of the drug as an effective sedative.

In the above ways the cognition of the lawyer parallels the cognition of the physician. When it comes to skepticism, however, the two paradigms diverge. While there are exceptions, and their number is growing, the court is traditionally wary of second-hand information, much more so than the physician. For instance, suppose that another physician's chart indicates that Dr. Now's new in-patient once complained of stomach pain, had an upper GI series, and was diagnosed as having a duodenal ulcer. In writing up the patient's orders Dr. Now would probably just assume that the new in-patient has a history of duodenal ulcer. In fact, Dr. Now would probably be considered less than thorough by his colleagues if he did not operate under this assumption. A judge, on the other hand, would consider this a rather sloppy way of doing things. The judge would ask the *patient* if the patient ever complained of stomach pain. The judge would want to *see* the radiograms for himself. He might give some credence to the chart itself *if* two witnesses could testify as to the authenticity of the physician's signature. But he would be much more interested in talking to the physician who wrote it. Is this your handwriting? Are you board certified in gastroenterology? While the judge is not always interested in the physical truth (for the reasons previously noted), when he is, he is much more particular about the source of his information than is the physician or the scientist in general.

The court is also much more careful than the physician, or scientist in general, when it comes to the problem of bias. Judges disqualify themselves, prospective jurors are dismissed, and changes of venue granted, all to make absolutely certain that everything possible has been done to assure that the law's fact finders are as unbiased as possible. But the physician is not under so urgent a mandate. It is not just that physicians are biased by their specialty, their experience, and their personal philosophies —everyone is biased. It is that physicians are not as concerned about it as the courts, which are paranoid by comparison. As a result, bias plays a bigger role in medicine than it probably should. This is most apparent in the case of functional disorders where the absence of gross organicity invites the personal prejudices of the diagnostician. The famous (or infamous) Rosenhan report[4] is just one example of the literature's indications that a psychiatric diagnosis may depend as much on who makes it as on the symptoms being displayed.

In summary, the courts are sometimes concerned with public policy rather than the truth, although they pretend to be seeking the truth for ritualistic reasons. The physician who does not understand that this is just a ritual, and that the ritual has a purpose, will have good reason to wonder about the court's rationality. Inversely, when the law *is* concerned with the truth, the courts will pursue it with a skepticism and abhorrence of bias that is often attributed to, but rarely found in, the scientific enterprises. The beginning of understanding is the realization that this has served the public well for centuries.

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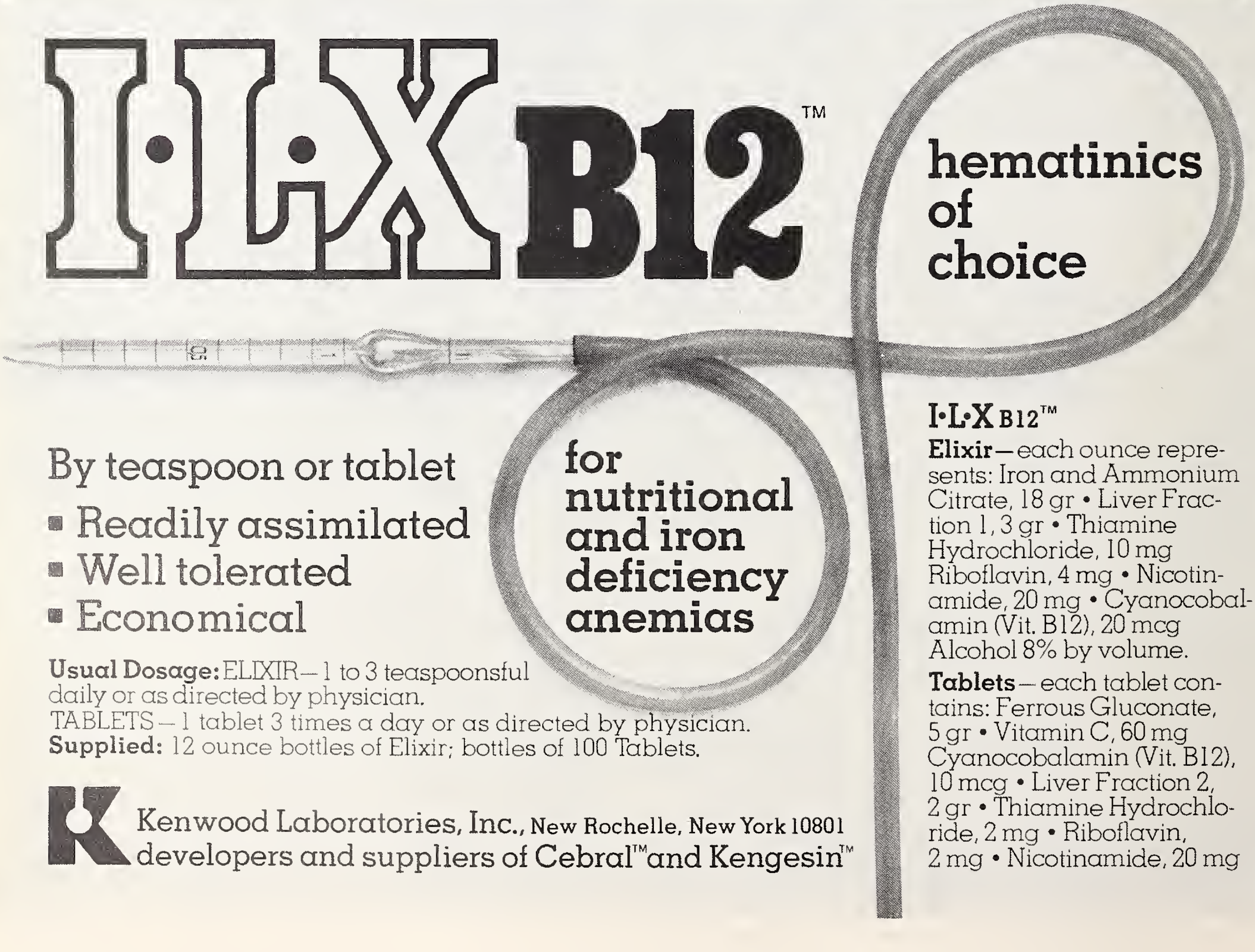

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Defending Malpractice Cases

James A. Harkins, M.D., J.D., F.C.L.M.

Defending Malpractice Cases

Medical malpractice cases were at one time a rarity, but this is not true today. Over the past several decades, there has been a mushrooming phenomena.

It seems incongruous that despite advances in medicine, upgrading of medical care and the ever improving quality of medicine, there are more medical malpractice cases each year.

What are the reasons, the causes, for this steadily increasing number of malpractice cases, growing by leaps and bounds year after year?

Why is it that the more highly trained, highly specialized and more diligent the practitioner is, the greater is his chance of being sued for medical malpractice?

There would appear to be no answer to this question, but, if we look to the basic roots, the pathogenesis of this problem, then this seemingly unconscionable relationship between skill and malpractice claims begins to make sense.

Medical malpractice suits were almost unheard of in the days of the horse and buggy doctor, equipped with the meanest of medical armamentarium.

Many of these nineteenth century practitioners were not graduates of medical schools but rather, learned their art of healing by first serving as observers, later as assistants to physicians and then gradually slipped into private practice.

One of the factors behind this spiraling rate of medical malpractice suits is specialization; and for three reasons.

First, the specialist is held to a higher degree of skill than the nonspecialist. Secondly, the specialist is not a part of his patient's life. The specialist does his job, sometimes never having seen the patient before the procedure is done (he took the patient on referral) and never seeing the patient thereafter. He is as a stranger to the patient.

Secondly, only the more difficult of cases are referred to the 'specialist', thus, it naturally follows that he will have a greater percentage of bad results than the 'family physician'.

The patient-plaintiff expects a miraculous cure when referred to a 'specialist'.

Thirdly, the well trained, cautious and adept specialist will undoubtedly examine and treat more patients than his counterpart, the 'family physician'.

It seems almost a badge of honor to be sued for malpractice in this day and age, since generally speaking, only the better qualified physicians are subject to such claims.

This seems obtuse, yet, is understandable when we take account of the lack of rapport which the highly trained 'specialist' has with his patients.

Dr. 'Quack' may have a very busy practice trading on his bedside manner, substituting warmth for skill. He is a confidant to his patient. He knows him well. He lives in the patient's home town. No one would ever think of suing good old Dr. 'Quack' since he's such a nice guy, and though he may not know what he is doing, has a warm relationship with his patients.

Dr. 'Quack' will never face a lawsuit. He is almost a member of the family.

But, in the case of the highly trained 'specialist', he is not a member of the patient's 'family'. He doesn't have that warm relationship with the patient which Dr. 'Quack' has. Thus, he is very vulnerable.

Another facet.

The patient-plaintiff is examined by the highly trained 'specialist' and treated for a brief period of time. After this treatment, his relationship with the 'specialist' is terminated. It is then easily seen that although no one would ever think of suing good old Dr. 'Quack' in malpractice, such patient-plaintiff may find it very easy to blame the 'specialist', despite the fact that he did the best he could, is highly trained and extremely cautious.

The 'specialist' is a stranger.

To most practitioners the specter of possible malpractice litigation seems always a 'thing that will happen to the next guy'.

Physician, do not be too complacent. For even though you may do your very best in treating a patient and even though you may use extreme caution and the most highly advanced techniques, you are vulnerable.

But, enough about that, let us go on to the possible defenses available to the physician who is sued for malpractice.

Most attorneys are poorly equipped to defend a physician in a medical malpractice case after graduation from law school (and remember there is no internship or residency in the practice of law): these lawyers may look to the bad result and feel that a defense is hopeless. Yet, there are certain technical defenses available and they should be

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used. The physician-defendant has as much right to use these defenses as any non-professional.

What the Physician Should Do When He Senses A Malpractice Action Against Him

At the very moment he senses a malpractice action as a possibility, he should get in touch with his malpractice insurance carrier. This is a must. Many malpractice policies contain a "caveat" that if the physician does not report the possibility of a medical malpractice action against him when he becomes aware of such threat, then the insurance company's duty to defend is deemed waived by the physician.

The next step that the physician must take is to try to talk the matter over with the plaintiff. He should try to explain that medical treatment carries no guarantee. Medical treatment is simply a rendering of services. Oftentimes, this 'talk with the possible plaintiff-patient' may result in the patient's better understanding of the problem and prevent the suit from being filed.

Also, it is a very good practice, in the case of the 'specialist', to speak with the referring physician, the family doctor. To tell him of the possibility of a lawsuit and mention that the referring physician may be caught up in this same malpractice suit; the basis being a claim of negligence on the part of the referring physician in sending the patient to the 'specialist'.

This will prove very effective in jogging the 'family doctor' into talking it over with the possible plaintiff-patient. It is in his interest to squelch the malpractice suit if at all possible. This is a most effective way of stopping a malpractice suit before it gets started, since the referring physician now realizes that he is possibly at risk as well as the 'specialist'. Further, the 'family doctor' will be much more effective in explaining that medical practice carries no guarantees, than would be the 'specialist'.

With these steps taken, the physician can only sit back and await the outcome of events.

What Technical Defenses are Available to the Physician Defendant

The physician-defendant has the right to use all of his technical defenses, just as any other persons. Among these technical defenses are "assumption of risk," "contributory negligence," Statute of limitations," "Res Judicata," and in most states, including Connecticut, the settlement of a patient-plaintiff's claim against the original wrongdoer (tort-feasor), will waive the plaintiff-patient's right to bring suit in malpractice against the defendant-physician who treated the patient for injuries sustained at the hands of the original wrongdoer.

This, based on the legal dogma that, "but for the negligence of the original tort-feasor, the plaintiff-patient would not have been required to consult the physician who maltreated him and suffer the damages done him by such treating physician."

When a patient settles his case, it is for all damages proximately caused by the original wrongdoer.

Let us examine these technical defenses one by one.

Assumption of Risk

This is a valid defense to a medical malpractice suit when the patient has been informed of the risks and no guarantee of results are given by the defendant-physician. This is especially true in cosmetic surgery since here, the patient-plaintiff could live his life out well, without such cosmetic surgery.

Here, the plaintiff-patient, in order to be made cosmetically whole, assumes the risk of contemplated surgery, if given a proper explanation of the dangers involved.

The defense of 'assumption of risk' lies on very tenuous grounds, since the defendant-physician has a greater knowledge of cosmetic procedures and dangers involved than does the plaintiff-patient. The mere fact that this discrepancy in knowledge exists may work to the disadvantage of the defendant-physician. Here, if the physician obtains a valid informed consent, exposure of the defendant-physician is lessened.

(This is the first of a series of two articles)

Uses of the Epidemiologic Method in Occupational Medicine

Edward J. Bernacki, M.D.

Occupational Medicine is primarily concerned with the prevention and treatment of diseases associated with existing environmental hazards, and research into potential risk factors associated with exposure to old or new agents. A number of disciplines are involved to achieve these ends, principally: toxicology, industrial hygiene, clinical medicine, and epidemiology. The latter, using data obtained on occupationally exposed groups, is the subject of this discussion.

The general strategy of the epidemiologic method is to describe morbidity and mortality in a population and to formulate and test hypotheses regarding the cause, prevention, and cure of diseases in man.[1] It is thus both descriptive and analytic, and used as such in Occupational Medicine.

Descriptive Epidemiology

A knowledge of environmental agents used in the work place, as well as a description of the morbidity and mortality of the population at risk is a necessary prerequisite in the formulation and testing of causal hypotheses or the establishment of preventive measures. These data are collected by means of prevalence surveys or by notification of occupational and non-occupational morbidity and mortality.

Prevalence surveys are perhaps the most widely used descriptive tool. Such data are simple to obtain usually accurate and precise in regards to measurements used, but unfortunately limited by the fact that erroneous causal conclusions may be drawn because they do not reflect the probability that a healthy individual will develop a disease, (i.e. incidence) but rather the probability that the individual will be found in the defined state at a point in time.[8]

The method is illustrated by a recent study in which Meurman et al, using a self-administered questionnaire measured dyspnea and cough among anthophyllite asbestos Miners and a control population. A threefold and twofold difference in the prevalence of dyspnea and cough respectively was noted between cases and controls.[6] Here a measuring device (the questionnaire) elicited specific information on the study population (the asbestos miners at a point in time.

Incidence data are available to the Industrial Epidemiologist in the form of ongoing reporting of illnesses or death and the continuous monitoring of pathologic or physiologic alterations in workers.

Such data may be causally defined, for example, asbestosis and coal workers' pneumoconiosis or manifestationally defined, examples being emphysema or angiosarcoma of the liver.[5]

Causally defined disease or mortality data are routinely collected by industrial medical departments and governmental agencies and primarily serve as an index of the adequacy of environmental controls.

Manifestationally defined mortality data are widely used in the formation of causal associations between death and various industrial toxicants. An example of their use is the study alluded to previously by Meurman et. al. Here, the frequencies of death from various causes were ascertained in the asbestos miners and compared with a control group to determine if significant excesses were recorded amongst the anthophyllite asbestos Miners.

In this and similar mortality studies, the data are easily available and the measured effect (death) is both accurate and reliable as is the specific cause.

Manifestationally defined morbidity data are another rich source of epidemiologic material but have been rarely used because corporate medical departments or governmental agencies have, until recently, been unable to collect them. Now, because some form of payment for medical care is provided to employees, and claims for this care usually record a number of parameters including a diagnosis, these data are becoming available for analysis by corporate medical departments or state or federal agencies concerned with occupational health.

Once collected, they can be used in the calculation of rates and then analyzed periodically to reveal the presence of secular trends or clustering in time and place. This type of monitoring enables investigators to rapidly detect subtle physiologic or pathologic alterations associated with the environment and based on this to institute preventive measures thereby limiting their occurrence.

This type of surveillance is illustrated by the work of Barbero and Flores who noted that an increasing number of individuals working in the hemp industry in and around Alicante, Spain, had chronic bronchitis. Tuberculosis was first suspected because of its high prevalence in the area, but x-rays and sputum

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DR. EDWARD J. BERNACKI, Corporate Medical Director, The Torrington Company, Torrington, Conn. and Lecturer in Epidemiology, Department of Epidemiology and Public Health, Yale University School of Medicine, New Haven, Conn.

cultures failed to support this and gave rise to the hypothesis that the disease was related to their environment specifically the inhalation of dust produced in the "batting" and "hackling" of cannabis sativa.[2] Further work by these authors and Bouhuys et al supported this hypothesis and gave rise to other hypotheses which have been tested and have demonstrated a mechanism by which this agent affects susceptible workers.[3]

Analytical Epidemiology

Hypotheses, generated by observing disease frequencies or from other sources such as industrial toxicology may be analytically tested by the use of case-control or prospective and retrospective cohort studies. Upon confirmation of a causal relationship by either method, experimental studies may be initiated or preventive measures applied.

Cohort studies are concerned with the probability of contracting a disease given that a person has been exposed. Whereas, case-control studies are concerned with the probability that a past exposure has occurred, given that an individual has a disease.[8]

In a prospective cohort study two cohorts are defined, those exposed and not exposed to an environmental agent. After comparability between the groups is assured, both are followed forward in time to determine if the proportion of diseased individuals among the exposed and non-exposed differ significantly.[5]

This approach is illustrated by Wagoner et al who identified five cohorts of uranium miners between 1950 and 1960 and compared their mortality experience for selected causes from the point of entry into the study onward, with a cohort composed of the male population of the Colorado Plateau, noting a significantly higher rate of lung cancer in the intensly exposed groups.[7]

A retrospective cohort study is similar to a prospective one, except that the disease and exposure have both occurred in the past. Meurman et al employed this technique by identifying a cohort of anthophyllite miners who worked in the mines between 1936 and 1967 and died prior to 1969 and comparing them to a cohort of controls matched for date of birth, death and sex. Both exposure and death occurred prior to the initiation of the study.[6]

Case-control analysis involves identification of comparable diseased and non-diseased groups which are analyzed to determine if the population exposed among the cases and controls differ.[5]

Hoover and Cole employed the latter method using newly diagnosed lower urinary tract cancer as cases and a random sample of area adults of the same age and sex as controls. Their analysis utilized risk ratios to demonstrate that a significantly greater proportion of the cases worked in hazardous occupations than did the controls.[4]

As presented above, the epidemiologic method is an indispensable tool in the practice of occupational medicine. Its usefulness lies in the fact that easily obtained data may be used to both monitor the industrial environment and define new disease entities leading to the prevention of environmentally induced disease. Together with industrial hygiene and toxicology it expands the level of knowledge of industrial diseases which is essential to the continuance of Occupational Medicine as a scientific endeavor.

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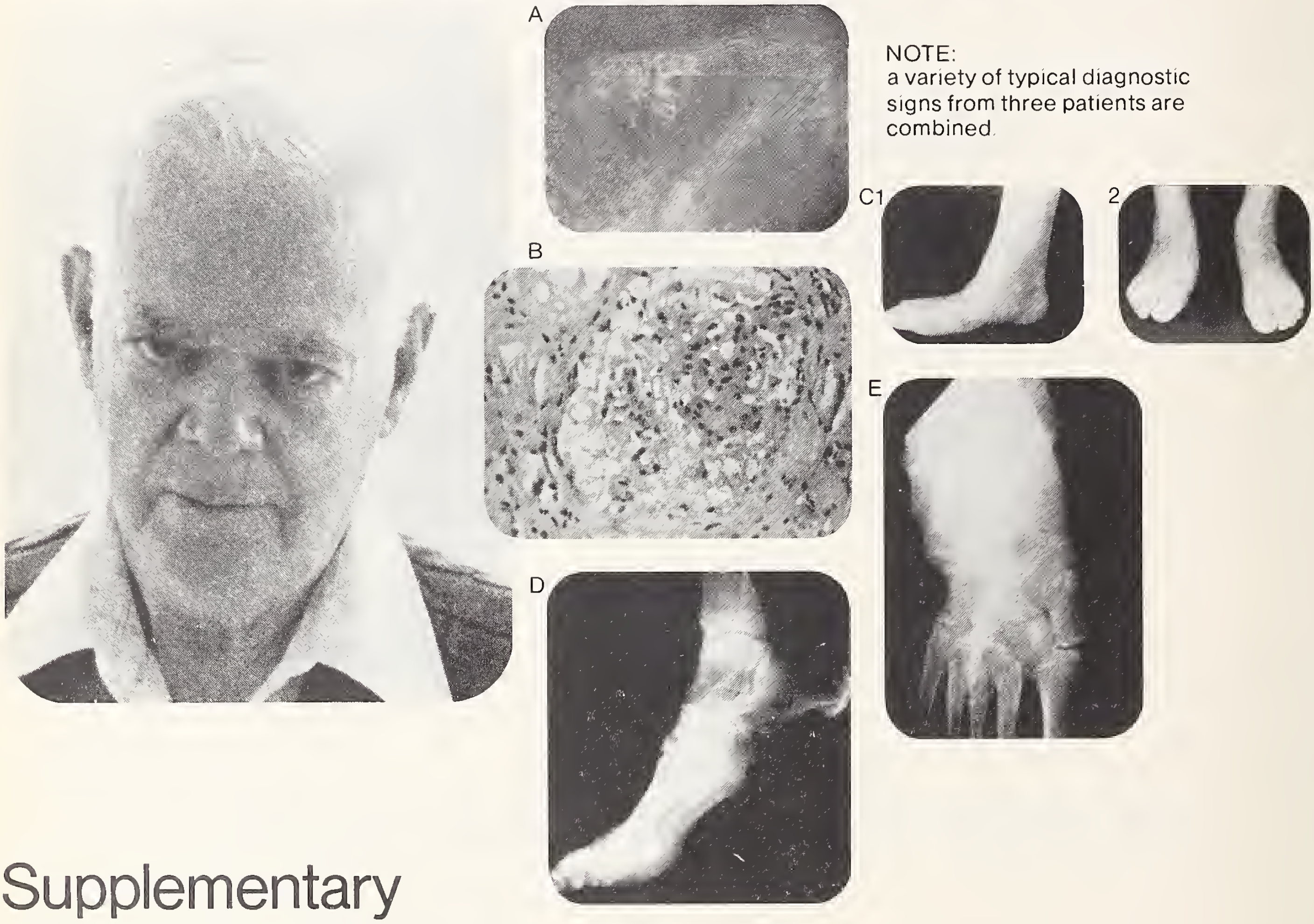

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Current Trends in House Staff Training

Wesley M. Vietzke, M.D.

Many major changes are occurring in house staff training, or graduate medical education, as its now designated. Rumors fly, misunderstandings abound; many are concerned, more confused. This report will attempt to clarify just what is and what is not happening, and put it in some historical perspective.

While there are evolving, in my view, what will prove to be major changes in the organization and supervision of the continuum of medical education, *i.e.* from admission to medical school to Board Certification, these reforms have progressed slowly over the past 10 years, and been approved at every turn by the AMA councils. They reflect a general consensus of perceived problems and appropriate solutions. While the free-standing rotating internship will be appropriately abandoned as ineffective and obsolete, flexible, integrated first year graduate experiences will be encouraged. The intent will be to train young doctors better for what they will do in practice. Perhaps, this all will be clearer, when reviewed in the context of the history of graduate education in this country during this century.

Historical Background

At the turn of the century many medical schools of extreme variability in resources turned out "M.D."s of diverse quality. These doctors then apprenticed, or went directly into practice. Others traveled to Europe for further education. Qualification, training and competence varied widely.

Following the 1910 Flexner report, which emphasized the Johns Hopkins model of European training, medical education in the medical schools which survived the report's impact adopted their present form of four year education following three or four years of college with an increased emphasis on solid basic science education and clinical experience. Following their gaining the M.D. degree most physicians began to take one or two years of internship, and then went into practice. Very few specialized. As late as 1930 there were three times as many interns as residents in our teaching hospitals.

Today the reverse is true. Since the second world war, the trend toward specialization has mushroomed, and practically every new graduate physician now takes three to five years of training after his M.D. degree.

However, the organization of this education has been chaotic. Accredited by their own review systems in cooperation with the AMA, the medical schools basically controlled the first four years, but abdicated responsibility for graduate training which the AMA and hospitals took responsibility for. The AMA Council on Medical Education (CME) Internship Committee and the American Hospital Association (AHA) accredited the internships which were free standing and related little to Medical School or residency. The specialty boards and the AMA accredited the residencies which also related to neither internship or Medical School. At the same time specialization increased, primary physicians decreased and the disorganization became more apparent.

During the mid-60's everyone became aware of this at once, it seems, and several large and prestigious examinations of the situation were done. I would like to discuss these studies in some detail, because the reports that came out of these studies have stimulated most of the changes reported here.

The Coggeshall Report

In 1965, the Association of American Medical Colleges (AAMC) published a report by Lowell T. Coggeshall, M.D. who was vice president at the University of Chicago. This report described and codified for the first time many of the problems in care delivery we all have heard so much about today—inequities, maldistribution, too many specialists, lack of continuity in care, and so on. It proposed that changes in medical education *per se* could change all this. Indeed it was called "Planning for medical Progress through Education" and it proposed that the Medical Schools so change and extend their power that they could occasion reform.[1]

Following a lengthy review of the history of American Medical Education, and consideration of current economic, political, and scientific trends, the Coggeshall committee made many recommendations, most of them directed to the end of strengthening the AAMC and the medical schools. Some of these recommendations, however, related directly to house staff training and its organization. Specifically Coggeshall suggested that:

> "Particular attention should be devoted to the developing improvements in the team approach in both hospital care and medical practice . . ." and
>
> "Particular effort should be made to provide leadership and aid in the development of improved approaches to family practice."[1]

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The "Millis" Report

One year later, in 1966, an AMA commissioned "Citizens Commission" made up primarily of prominent educators and laymen published a report on house staff training. This report, usually called the "Millis report," after the president of the Commission, John Millis, who was then president of Western Reserve University, again reviewed the current chaotic situation and called for several important reforms in house staff training:

These were:

(1) Education of primary care physicians with a new curriculum emphasizing ambulatory medicine.

(2) More administrative and educational continuity in the six to eight years of undergraduate-graduate education.

(3) More university (medical school) supervision and input into house staff education.

To occasion these changes, several important steps were suggested by the Commission:

(1) abandonment of the free-standing rotating internship. (Free-standing implied that the internship related to no residency program or university.)

(2) development of university supervised house staff programs, conceived in educational terms, with specified objectives and evaluative programs.

(3) development of residencies in primary care.

(4) development of a new national body to coordinate and supervise medical education in general and these reforms in particular.[2]

Also in 1966, another AMA selected committee chaired by Dr. W. R. Willard published a study which urged establishment of family practice as a new specialty.[4] And in 1969 a Board of Family Practice was established, and the American Academy of General Practice became the American Academy of Family Physicians.[5]

In 1970 the AMA Council of Delegates approved the third of a series of proposals directed toward integration of internships and residency and in effect, ended approval of free-standing internships by 1975. In 1972, the AAMC Council of Deans assumed university supervision for all residencies,[3] and two new Liaison Committees to supervise medical education have just been formed with representatives of AMA, AAMC, American Board of Medical Specialities, The Council of Medical Specialties, and the American Hospital Association. One supervises medical education in general, the other graduate education. These groups have begun to function and are assuming responsibility for accreditation of medical schools, as well as residencies. "Internships" will henceforth also be approved by these bodies, but as "flexible" or "categorical" experiences related to specific residency and specialty board requirements, according to guidelines approved in 1972 by the AMA.[6]

The "Gap Report" of the NBME

Another recent report has also received much attention, and will undoubtedly receive more in the future. This is the Report of the Committee on Goals and Priorities (GAP) of the National Board of Medical Examiners published in 1973.[7] This report, developed by a special advisory committee to the NBME, chaired by William B. Mayer, M.D., Dean of the University of Missouri-Columbia School of Medicine, again reviewed the problems of discoordination and discontinuity in medical education, but this time from the perspective of evaluation, testing, and licensure. They recommended "that the National Board of Medical Examiners support the development and coordination of a comprehensive policy for evaluation of professional competence throughout the continuum of medical education."[7]

Specifically, they recommended that "the NBME, in cooperation with the Federation of State Medical Boards, should develop an examination (Qualifying A) to evaluate performance characteristics requisite for providing patient care in a supervised setting. This examination should be administered at or near the end of undergraduate medical education," and " . . . In association with participating specialty boards, the NBME should develop examinations (Qualifying B) to be given at the completion of formal graduate education to evaluate performance characteristics requisite for independent medical practice."

In other words, licensure would come upon passing of specialty Boards and the current National Boards would only certify competence to enter house staff training. These recommendations have not been acted upon. They are, however, receiving active attention from the various groups which comprise the new governing bodies.

These suggestions, too, reflect a phenomenon which is already well established. A recent study showed that 99% of 1960 graduates surveyed took residency training and 70% have now been certified in their specialties.[8]

Current Status

Thus in 1974, many changes in the organization coordination and accreditation have already taken place. There will be no more free-standing rotating internships. House staff programs will be increasingly university-related, and hopefully reflect a continuum of education tailored to the student's career aspirations.

Residency programs in Family Medicine are being established and their numbers will gorw. Programs in general (primary care) medicine and pediatrics will also receive more emphasis. Ultimately fifty percent of all house offices will be in these primary care training programs, another trend recently endorsed by the AMA's Council of Delegates.

On the local level, the University of Connecticut School of Medicine has developed educational standards for graduate education, and is working with hospitals in the greater Hartford area as well as elsewhere in Northern Connecticut to further cooperation in graduate education.[10] This has proven an evolutionary, gradual process, but does offer promise of providing a solid integrated clinical educational program to undergraduates and house officers in the future.

Conclusion

The scene in graduate education is changing, locally and nationally. These changes reflect both organized medicine's and the public's perception of the changing requirements for medical care. These trends also reflect attempts to better coordinate the continuum of medical education. Some of the implications of these trends are clear. There will be more university involvement in graduate education, both locally and at the national policy level. It is very likely board certification will be required for licensure. However, these trends are already well-established, and no dramatic or sudden change is likely. There will simply be more formal recognition of what has been gradually happening over the past two decades, largely under the auspices and with the leadership of the AMA and its Council on Medical Education.

REFERENCES

1. Coggeshall Lowell T: "Planning for Medical Progress Through Education," A Report submitted to the Association of American Medical Colleges, AAMC, Evanston, 1965

2. "The Graduate Education of Physicians" The Report of the Citizens Commission on Graduate Medical Education, American Medical Association, Chicago, 1966

3. "Implications of Academic Medical Centers Taking Responsibility For Graduate Medical Education," *J. Med. Education:* 47:77-84, 1972

4. Meeting the Challenge of Family Practice, Ad Hoc Committee on Education for Family Practice, American Medical Association, 1966

5. Rousselot Louis M: "Federal Efforts to Influence Physician Education, Specialization Distribution Projections and Options," *Am. J. Med:* 55:123-130, 1973

6. "Some Recent Events of Special Interest to Medical Education" *JAMA*, 1972 222:962-964

7. Evaluation in the Continuum of Medical Education, Report of the Committee of Goals and Priorities of National Board of Medical Examiners, Philadelphia, 1973

8. Levitt Edithe J, Sabskin, Melvin, and Mueller, C Busber, "Trends in Graduate Medical Education and Specialty Certification," *NEJM*. 290:545-549, 1974

9. "Recent Events of Special Interest to Medical Education," *JAMA:* 226:894-897, 1973

10. Vietzke WM, "Standards for Graduate Education," letter to the editor, *J. Med. Ed.*, 49:91-92, 1974

ARTISTS ATTENTION

We regret that exposition of the art works from our organization cannot be held this year. The Art Committee has determined that due to the fact that the Annual Meeting of the Connecticut State Medical Society will only be two days this year, there is no practical way that art works can be displayed, judged, and returned in this short time. We are optimistic about 1976 plans however.

Stewart J. Petrie, M.D.
President
Protem Art Committee

LABORATORY NOTES

Malignant Melanoma

The following Table represents our updated classification of melanomas:

	Hutchinson's Melanotic Freckle	*Melanoma, Superficial Spreading*	*Invasive Melanoma*
Gross	Usually 4-6 cm across not ulcerated	Usually 2.5 cm or less across may be ulcerated	Nodular May be polypoid Early ulceration
Micro			
Pigment	Profuse	Variable	Variable
Root Sheath involvement	+	-	-
Epidermal melanocytes	marked pleomorphism	No	No
Edges	Pre-existing junctional change	Pre-existing junctional change	No pre-existing junctional change. May invade epidermis
Levels of invasion	Confined to epidermis until late	Same	Invasive from onset
Classification of level of invasion	1. Confined to epidermis 2. Involves papillary dermis 3. Involves reticular dermis 4. Invades subcutaneous tissue or deeper		

M. Yi, M.D.
R. Barnett, M.D.

CPK Isoenzymes and Myocardial Infarction

Total CPK (creatine phosphokinase) may be elevated in a variety of conditions and is therefore not diagnostic of myocardial infarction. For example Garcia[1] points out that heavy muscled athletes may have high CPK because of their muscle mass alone. Hospital patients frequently receive injections into their muscles and this raises total CPK.

A more specific test now available[2] separates the three CPK isoenzymes, namely (from cathode to anode) CPK III (skeletal muscle), CPK II (heart muscle) and CPK I (CNS). Our test gives a qualitative estimation of CPK II. Normally absent from the serum, it appears within 6 to 30 hours after myocardial infarction, and is most often positive when total CPK is elevated.

Report will indicate CPK II *present* or *absent*, and will also give total CPK. Order as *CPK isoenzymes*. V. B. Kambli, Ph.D.

1. Garcia W: JAMA *228*, 1395, 1974.
2. Sobel BE: JAMA *229*, 201, 1974.

Single Donor Platelets

The Red Cross can now provide platelets from a single donor in a container equivalent to 7 to 10 single units of platelet concentrate. This is indicated primarily to avoid immunization and development of a refractory state. It is therefore chiefly for patients who are entering on a course of platelet transfusion, or who are already refractory to multiple donor concentrates. The product is expensive ($100) and must be used within 24 hours of collection.

Phenothiazine Screening Test for Urine

A screening test for phenothiazine derivatives in the urine can be used to determine whether or not a patient is taking the medication prescribed. Phenothiazines commonly used at Norwalk: thorazine, compazine, sparine, stelazine, trilafon, temaril, mellaril and phenergan have been detected.

Each phenothiazine derivative yields a characteristic color when reacted with test reagents ferric chloride, perchloric acid and nitric acid. A first morning urine specimen is required for testing. Drug intake of over 5 mg/day should give a positive test

Maryellen Peracca, M.D.

ROY N. BARNETT, M.D., Editor, *Laboratory Bulletin*, Norwalk Hospital.

Anaerobic cultures

An excellent series of NEJ Med Medical Progress articles on anaerobic infections contains many practical hints.[1] Among them:

"*Unacceptable* specimens are contaminated by the commensal flora of mucocutaneous surfaces—."

"*Acceptable* specimens include the following body fluids that are normally sterile : – abscess contents; blood cultures; deep aspirates of wounds—."

"—Certain specimens have a very low yield of anaerobes - i.e., urine and cerebrospinal fluid."

Certain "moderate" anaerobes survive small exposures to oxygen; other "fastidious" ones require the utmost care to avoid any oxygen.

For most purposes published susceptibility to antibiotics are more reliable than susceptibility testing by normal techniques.

We are happy to furnish special tools and instructions for taking anaerobic cultures.

For certain specimens i.e. wounds, abscesses we automatically culture for anaerobes as well as aerobes.

A. C. Noto, M.D.

The $100 Aspirin Tablet

One of our first platelet aggregometry studies yielded a "no second wave" pattern strongly suggestive of aspirin effects. The patient originally denied the medication but finally recalled ingesting two aspirins about 24 hours before the test.

Moral: Aspirin has a strong and quite lasting effect on platelet aggregation. It should not be administered for *1 week* before platelet aggregometry, otherwise the test results mean nothing.

Small helpful hints

1. If you write your own Bacteriology slips make sure the patient's name and your name are legible.
2. Spraycyte is available at the front desk of the laboratory for preserving cytology smears. It is much more convenient than standard alcohol-ether and gives equally good results.

"Keep vein open"

This common order is a major cause of venous thrombosis! We urge that new IVs be started when needed, rather than leaving in a slow drip which is often infected or thrombosed just when it is desperately needed.

Welcome, New Members

Continued from Page 121

Windham County

Eui K. Chung, M.D., Pomfret Road, RFD No. 1, Putnam, Conn. 06260
Marvin C. Ehrlich, M.D., 70 Mansfield Avenue, Willimantic, Conn. 06226
Stanton D. Hale, M.D., 150 Mansfield Avenue, Willimantic, Conn. 06260
John B. Hewetson, M.D., Day Kimball Hospital, Putnam, Conn. 06260
Sangwun Lee, M.D., 132 Mansfield Avenue, Willimantic, Conn. 06226

Fairfield County

Zosimo A. Adefuin, M.D., 1475 Barnum Avenue, Bridgeport, Conn. 06610
Milan Beres, M.D., 881 Lafayette Street, Bridgeport, Conn. 06604
Robert M. Biondi, M.D., 149-153 East Avenue, Norwalk, Conn. 06851
Robert T. Blabey, Jr., M.D., 70 Mill River Street, Stamford, Conn. 06902
Jolan W. Blass, M.D., 173 Hubbard Avenue, Stamford, Conn. 06905
Nicholas G. Bottiglieri, M.D., American Cancer Society, 965 Hope Street, Stamford, Conn. 06907
Paul W. Brown, M.D., St. Vincent's Hospital, Bridgeport, Conn. 06606
Spencer F. Brown, M.D., Department of Health, Darien, Conn. 06820
Carleton Campbell, M.D., Nod Hill, Wilton, Conn. 06897
Colin B. Cook, M.D., Fairfield Hills Hospital, Newtown, Conn. 06470
Paul M. Feuer, M.D., 1305 Post Road, Fairfield, Conn. 06430
Michael A. Friedman, M.D., 144 Morgan Street, Stamford, Conn. 06905
William I. Geftner, M.D., St. Joseph's Hospital, Stamford, Conn. 06904
Charles D. Gianetti, M.D., 3715 Main Street, Bridgeport, Conn. 06606
Robert C. George, M.D., 10 Mott Avenue, Norwalk, Conn. 06850
Leonard H. Goldstein, M.D., 84 Locust Avenue, Danbury, Conn. 06810
Robert M. Gossart, M.D., 782 Clinton Avenue, Bridgeport, Conn. 06604
William M. Griffin, M.D., 49 Lake Avenue, Greenwich, Conn. 06830
Edward A. Griffiths, M.D., 1 Atlantic Street, Stamford, Conn. 06901
Barry R. Keller, M.D., 84 Locust Street, Danbury, Conn. 06810
Kwi Sook Choi Kim, M.D., 50 Ridgefield Avenue, Bridgeport, Conn. 06610
Robert N. Kitchen, M.D., 8 West End Avenue, Old Greenwich, Conn. 06870
Madeline Klein, M.D., 40 Grove Street, Ridgefield, Conn. 06877
Roger A. LaGratta, M.D., 85 Osborne Street, Danbury, Conn. 06810
Hee Jong Lee, M.D., 226 Mill Hill Avenue, Bridgeport, Conn. 06610
Jack J. Levy, M.D., 830 State Street, East, Westport, Conn. 06880
Chun Bun Lo, M.D., 108 East Avenue, Norwalk, Conn. 06851
Richard M. Margules, M.D., P.O. Box 426, Newtown, Conn. 06470
Diane W. Mickley, M.D., 239 Glenville Road, Greenwich, Conn. 06830

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[1] Gorbach S L and Bartlett J G: NEJ Med *290,* 1177, 1237 and 1289, 1974.

FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, Conn. 06511
Telephone 865-0587

Francis G. Sweeney
Assistant Executive Director
Public Affairs

William R. Richards, M.D.
Executive Director
Josephine P. Lindquist
Associate Executive Director

Leonard R. Tomat
Assistant Executive Director
Scientific Activities

Summary of Actions
Council Meeting

I. Attendance

Present in addition to the Chairman, Dr. D. A. Grendon, and the Vice Chairman, Dr. Carl W. Johnson, were: Drs. Root, Jr., VanSyckle, Backhus, Brandon, Nolan, Gardner, Fabro, Bradley, Hess, Cramer, Granoff, Rubinow, Ragland, Jr., James, Freedman, Kamens, McGarry, Harkins, Mendillo, Eslami, Barrett and Sonnen.

Also present were: Mrs. Lindquist, Mr. Tomat, Mr. Sweeney and Dr. Richards.

Absent were: Drs. Spitz, Hecklau, Krinsky, Dambeck, Roch, Canzonetti, Sadowski, Magram and Klare.

II. Routine Business

Life Memberships

It was VOTED to approve applications for Life Membership received from the following eligible Active Members:

Fred C. Barald, 22 Belcrest Road, West Hartford
John T. Beebe, 85 Jefferson Street, Hartford
Kenneth F. Brandon, 128 Oxford Street, Hartford
Chaim E. Bruskin, 1840 Park Street, Hartford
John E. Darrow, 55 West Main Street, New Britain
William J. Doerr, 690 Prospect Avenue, Hartford
Joseph F. Dushane, 85 Jefferson Street, Hartford
Walter F. Jennings, Sapphire Beach, Apt. 18, St. Thomas. V.I.
Aaron Levy, 26 Elm Street, Winsted
Alexander Marsh, 1615 Stanley Street, New Britain
A. Benjamin Rafkind, 212 Hunting Hill Avenue, Middletown
Moe B. Rosenthal, 1680 Albany Avenue, Hartford
Isadore Rothstein, 90 Haynes Road, West Hartford
A. Frederick Serbin, 21 Woodland Street, Hartford
Mark Thumin, 760 Saybrook Road, Middletown

Date of Next Meeting

The next meeting of the Council will be held on Wednesday, January 15, 1975.

III. Old, New and Special Business

Election of Student Members

It was VOTED to elect to Student Membership ten Connecticut residents who are enrolled in American medical schools and two graduate M.D.s who are serving internships or residencies in Connecticut hospitals. The names of those elected will be published in an early issue of the Journal.

MCMA Resolution re "Medicare Payments"

Consideration was resumed (from the last meeting) of two documents as follows: (a) A resolution introduced by the Middlesex County Medical Association (W.R. James, Councilor) which advocated that the Society change its policy from "usual, customary and reasonable charges" to "a uniform schedule of indemnity payments" as the basis for compensating physicians for services rendered to Medicare beneficiaries; and (b) a report (including an opinion of CSMS legal counsel) submitted by the Committee on Third Party Payments which, in effect, advocated that the subject policy of the Society not be changed. A motion to refer the resolution to the House of Delegates recommending approval was lost. No other action was taken.

Resignations, Appointments, Etc.

(a) *Committee on VD Education and Control:* It was VOTED to accept the resignation of Allen R. Traurig, Waterbury, as a member of the Committee.

(b) *CSMS—Designates on CRMP Advisory Board:* It was noted with regret that Morris A. Granoff, New Haven, did not wish to continue his service as a member of the CRMP Board and Executive Committee after the expiration of his current term on 12/31/74. It was VOTED to accept, with regret, the decision of Kurt Pelz, Clinton, to resign as a member of the CRMP Advisory Board and Executive Committee, effective 12/74. Dr. Pelz term will expire 12/31/76. It was further VOTED to designate J. Alfred Fabro, Torrington, to replace Dr. Granoff as a member of the CRMP Advisory Board and Executive Committee for a full term, 1/1/75-12/31/77 and to designate Orvan W. Hess, New Haven, to replace Dr. Pelz as a member of the Advisory Board and Executive Committee for the balance of a term, 1/1/74-12/31/76.

(c) *Committee on Continuing Medical Care and Rehabilitation:* It was VOTED to accept the resignation of Thomas F. Coyle, Bridgeport, as a member of the Committee.

(d) *Committee on Accident Prevention and EMS:* It was VOTED to accept the resignations from the Committee of two members as follows: Michael A. Browne, Stamford, and Ruben Fialkoff, Manchester.

(e) *Liaison Committee with Connecticut Bar Association:* It was VOTED to accept with regret the resignation of Harry P. Engel, Bridgeport, as chairman and as a member of the Committee. It was further VOTED to request the President, the President-Elect and the Chairman of the Council to seek a joint meeting with their counterparts in the Connecticut Bar Association for the purpose of discussing the future of the subject Liaison Committee (which has been almost totally inactive during the past several years.)

(f) *Committee on Allied Medical Services:* It was VOTED to appoint Howard J. Wetstone, Hartford, to membership on the Committee.

(g) *Committee on Public Health:* It was VOTED to accept the resignation of Mario L. Palmieri, Middletown, from membership on the Committee.

(h) *Councilor, FCMA:* Received with regret was notice given by Edmund F. Hecklau, Greenwich, that he is resigning as Councilor of the Fairfield Association.

"Consortium" of Yale's Connecticut Cancer Center

It was VOTED to receive as information a verbal presentation made by E. Tremain Bradley, chairman of the Cancer Coordinating Committee, which covered the "Follow-Up of Cancer" brochure, the status of the Connecticut Cancer Epidemiology Unit and the progress that is being made toward creating the "Connecticut Cancer Center" which was awarded to the Yale University School of Medicine to implement. In conjunction with the latter item of his report, Dr. Bradley noted that a "Consortium" of interested health organizations was being developed by the implementers of the Cancer Center. On his recommendation, the Council VOTED to approve membership of the Society in such consortium.

Delay in Medicaid Payments

At the request of the President, this item was placed on the agenda for updative discussion. Note was made that Governor Meskill, the Welfare Commissioner, the Commissioner of Finance and Control and Governor-Elect Grasso had been apprised by letter of the subject action of the House of Delegates on November 20 and that, thus far, no responses had been received from any of those persons. It was VOTED to ask Dr. Leo Giardi, Hartford, to report in writing to the Council, for presentation at the next meeting, on past and current discussion he and/or his Liaison Committee has had with the Welfare Commissioner and/or his staff concerning the ongoing delay in payments to providers of health services to Medicaid beneficiaries.

CSMS Sponsorship of Medix TV Series

Having been apprised by the Assistant Director for Public Affairs, Mr. Sweeney, that it had been learned that a contingency of co-sponsoring with the Burroughs Wellcome Pharmaceutical Company the Medix (Health Education) TV Series on Connecticut stations would be to allow the Company to promote one or more of its products, the Council VOTED to disapprove the co-sponsorship under such a contingency. Note was made that the Company had declined to allow the Society to disclaim (on the air or elsewhere) that the Society's co-sponsorship of the program did not necessarily imply CSMS endorsement of BW products.

Policy re Refund of Dues of Deceased Members

Having discussed this question in a general way at a previous meeting, and having been apprised that the Board of Governors of the New Haven Association "favored the principle of granting dues refunds to the estates of deceased members only upon request for same by said estates," it was VOTED to accept for filing the subject communication of the NHCMA Board of Governors and it was further VOTED to adopt as policy that the Society act on requests for the refund of dues in case of death of a member in accordance with the action and recommendation on the request approved by the member's component County Medical Association.

Information re "Full-Time Chiefs of Service"

Provided by Howard Levine, New Britain, it was VOTED to accept for filing information concerning the policy of the Residency Review Committee in Internal Medicine on the subject of full-time chiefs of service; i.e., that while full-time chiefs are not required as a contingency of approval of resident training programs in internal medicine, they definitely strengthen such programs. It was further VOTED to refer this information to the Council's ad hoc committee which has undertaken a study of all aspects of full-time chiefs of service in Connecticut hospitals.

Report—Committee on Continuing Medical Care and Rehabilitation

It was VOTED to accept for filing a report submitted by the Committee which indicated that a review had been made of both general and specific aspects of the quality of medical care rendered to patients in Connecticut extended care facilities, certain regulations (directives) which have been recently been issued by the State Department of Health pertaining thereto and several letters received from members of the Society protesting about the impact that several of the latter regulations may have on their personal practice patterns and/or right to make individual judgments in their care of such patients. The Committee's reported subject opinions were in general support of the regulations issued by the Health Department and advocated Council adoption by the Board of Directors of HCMA on 10/2/74. It was further VOTED to approve the Committee's report and to adopt the HCMA statement (slightly amended) as follows:

> "The Council of the Connecticut State Medical Society believes that care of patients in chronic and convalescent nursing homes is of the utmost importance. It recognizes that as the incidence of chronic disease has increased, and as the number of patients in these facilities has increased, physicians and organized medicine have exerted insufficient leadership in assuring that the quality of care to patients in these facilities is superior.
>
> "The Council notes the letter of June 3, 1974 from Health Commissioner Dr. Douglas Lloyd to administrators of chronic and convalescent nursing homes in which he reports instances when physicians have not attended patients in distress, have failed to take due care in ordering medications or have failed to carry out the diagnostic or management procedures necessary to assure their patients' health and safety.
>
> "The Council endorses this letter from Commissioner Lloyd and, in support of it, makes the following recommendations:
>
> 1. That chronic and convalescent nursing homes obtain the services of a physician medical director whenever this is possible.
> 2. That this director assume the responsibility for assuring that the quality of care to patients in the facility is excellent.
> 3. That instances in which the director feels that physicians attending patients in the facility are not rendering adequate care be reported to the County Medical Association of which the physicians are members for appropriate investigation and action.
> 4. That physicians attending patients in these facilities who feel that because of restraints of time or for other reasons, they cannot adequately attend their patients should transfer their responsibility to a colleague or to the medical director of the facility."

N.B.: Members of the Committee on Continuing Medical Care and Rehabilitation knew of no way of conducting quality of care assessment other than by chart and bedside review of patient care. Members involved in long-term care were impressed by the complex diseases and supportive care involved in so-called "custodial" care patients. The infrequency of certain physicians' visitation in long-term care was still a vexatious problem to members of the committee holding medical directoral responsibility.

Report—Committee on Legislation

It was VOTED to accept for filing a report of the Committee concerning health education in the schools. It was further VOTED to approve a recommendation of the Committee, with an amendment offered by Dr. Root for the Committee on Statewide Medical Planning, as follows: That the Council contact the State Departments of Education and of Health, asking that a joint committee of the three organizations be formed to study ways of implementing a meaningful program of health education in the public school system.

Report—Chairman, Committee on Allied Medical Services

It was VOTED to accept for filing a report submitted by Hilliard Spitz, New London, chairman of the Committee, concerning discussions he and other interested persons had had with Mr. Roland E. Schmidt, Legislative Consultant on Health to the General Assembly's Committee on Public Health and Safety, on the subject of a "joint (common) practice act" for all deliverers of health care services in Connecticut. It was recalled that such a joint practice act and common examining board were recommendations of the 1970-71 Etherington Report. Dr. Spitz reported that he and representatives of the Connecticut Nurses' Association spoke in opposition to the proposal on the grounds that there is not enough in common (education, training, scope of responsibility, etc.) to warrant the establishment of a single examining board or the writing of a joint practice act. It was further VOTED to bring Dr.

Spitz's report to the attention of the Society's Committee on Legislation with instruction to work in opposition to bills implementing the foregoing Etherington Committee objectives should such bills be introduced at and considered by the 1975 session of the General Assembly.

Verbal Reports on Portland (Ore.) AMA Meeting

Various members of the "Connecticut Delegation" gave verbal reports, some reflecting a difference of opinion, on various happenings at the meeting of the AMA House of Delegates in Portland, Oregon, 11/30-12/4/74. Stressed were: The AMA's poor financial situation; the House's rejection of the Board of Trustees' recommendations concerning the curtailment of publications, the elimination of many committees and councils and the discontinuance of accepting advertising (principally pharmaceutical) for AMA publications and a $90 dues increase; and the House's action to assess all dues-paying members $60 to tide the organization over until the question of a dues increase can be acted on definitively (for 1976) at the annual meeting in June. It was VOTED to request Norman H. Gardner, East Hampton, former AMA Vice President, to present to the Council at the next convenient meeting his impressions of how the AMA Board of Trustees and Staff function, based on his experience as a member of the Board.

Report re Commission on Hospitals and Health Care

It was VOTED to accept for filing an activities report submitted by Sidney L. Cramer, Hartford, CSMS representative on the Commission. In brief, the report noted that the Executive Director of the Commission, Mr. John Doyle, has resigned his post and that at least three persons are believed to be interested in being considered for the post. The Executive Director is selected by vote of the members of the Commission . . . also, that a study of primary care has been under way (via a task force) for some time but that, as of the present, the study is quite incomplete and that no conclusions are being drawn.

Report on AAMSE Meeting on "Malpractice Problems," Portland, 11/30/74

It was VOTED to accept for filing a report submitted by Mr. Tomat, CSMS Staff, on the proceedings of a subject meeting sponsored by the American Association of Medical Society Executives, held in Portland, Oregon, in conjunction with the recent AMA meeting. The report indicates that while the CSMS-Aetna Program has not "licked" the malpractice problem in Connecticut, the situation is less desperate here than in many states throughout the country where coverage is not obtainable in-state at all and/or where premium rates are substantially higher. Experimentation with arbitration panels is being conducted and investigation is being conducted of the feasibility of applying the "no-fault" principle to professional liability insurance. Copies of the report are to be distributed to members of the CSMS Committee on Professional Liability.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on Dec. 19, 1974. Detailed minutes of the meeting are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

1975 ANNUAL MEETING
CONNECTICUT STATE MEDICAL SOCIETY

APRIL 30, MAY 1, 1975—HARTFORD HILTON HOTEL—HARTFORD

WEDNESDAY, MAY 1—HOUSE OF DELEGATES MEETING

THURSDAY, MAY 2—SCIENTIFIC PROGRAM & SECTION MEETINGS

HIGHLIGHTS OF SCIENTIFIC PROGRAM

SYMPOSIUM ON WHAT YOU NEED TO KNOW ABOUT BREAST CANCER—1975

Why doesn't every woman get breast cancer?
How do you find the woman with breast cancer?
How much help is the pathologists?
What about hormones?
So she has breast cancer, now what?

PLAN NOW TO ATTEND

In Memoriam

Clancy, John J., Yale Medical School, 1936. Dr. Clancy was a practicing internist in the Hartford area since 1939, and served in the U.S. Naval Reserve 1941-1942. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society. Dr. Clancy died December 9, 1974, at the age of 64.

Colwell, Howard S., Johns Hopkins Medical School, 1914. Dr. Colwell was a retired specialist in internal medicine. At one time, he worked for the Rockefeller Foundation in the British West Indies as a member of the Instructive Health Board, and was a veteran of World War I, having served in the Medical Corps. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Colwell died December 21, 1974, at the age of 86.

Landry, Benedict B., Harvard Medical School, 1920. Dr. Landry was a former president of the surgical and medical staff at St. Francis Hospital, and an Army veteran of World War I. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society. Dr. Landry died December 11, 1974, at the age of 78.

Paul, Francis, University of Munich, Germany, 1924. Dr. Paul was a practicing psychiatrist in the Fairfield area since 1924. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Dr. Paul died July 1, 1974 at the age of 75.

Robinson, Albert J., University of Toronto, 1923. Dr. Robinson was practicing insurance medicine prior to his retirement in 1964. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Robinson died December 5, 1974, at the age of 75.

Semmelmeyer, John Albert, III, Washington University, 1958. Dr. Semmelmeyer was a practicing internist in the Fairfield area since 1965. Dr. Semmelmeyer was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Semmelmeyer died October 1, 1974, at the age of 42.

Smith, Harold, Columbia Medical School, 1915. Dr. Smith was a Lieutenant in the Marine Corps during World War I. He was a member of the Middlesex County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Smith died July 9, 1974 at the age of 83.

Thenebe, Carl L., University of Pennsylvania, 1918. Dr. Thenebe was a practicing pediatrician in the Hartford area until his retirement in 1968. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Thenebe died December 4, 1974, at the age of 80.

Tinkess, Donald E., McGill University, 1925. Dr. Tinkess was a practicing ophthalmologist in the Fairfield area since 1925. He was a veteran of World War II and formerly practiced in Greenwich, Conn. where he served on the staff of the Greenwich Hospital. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Tinkess died May 13, 1974, in Lookout Mountain, Tennessee, at the age of 72.

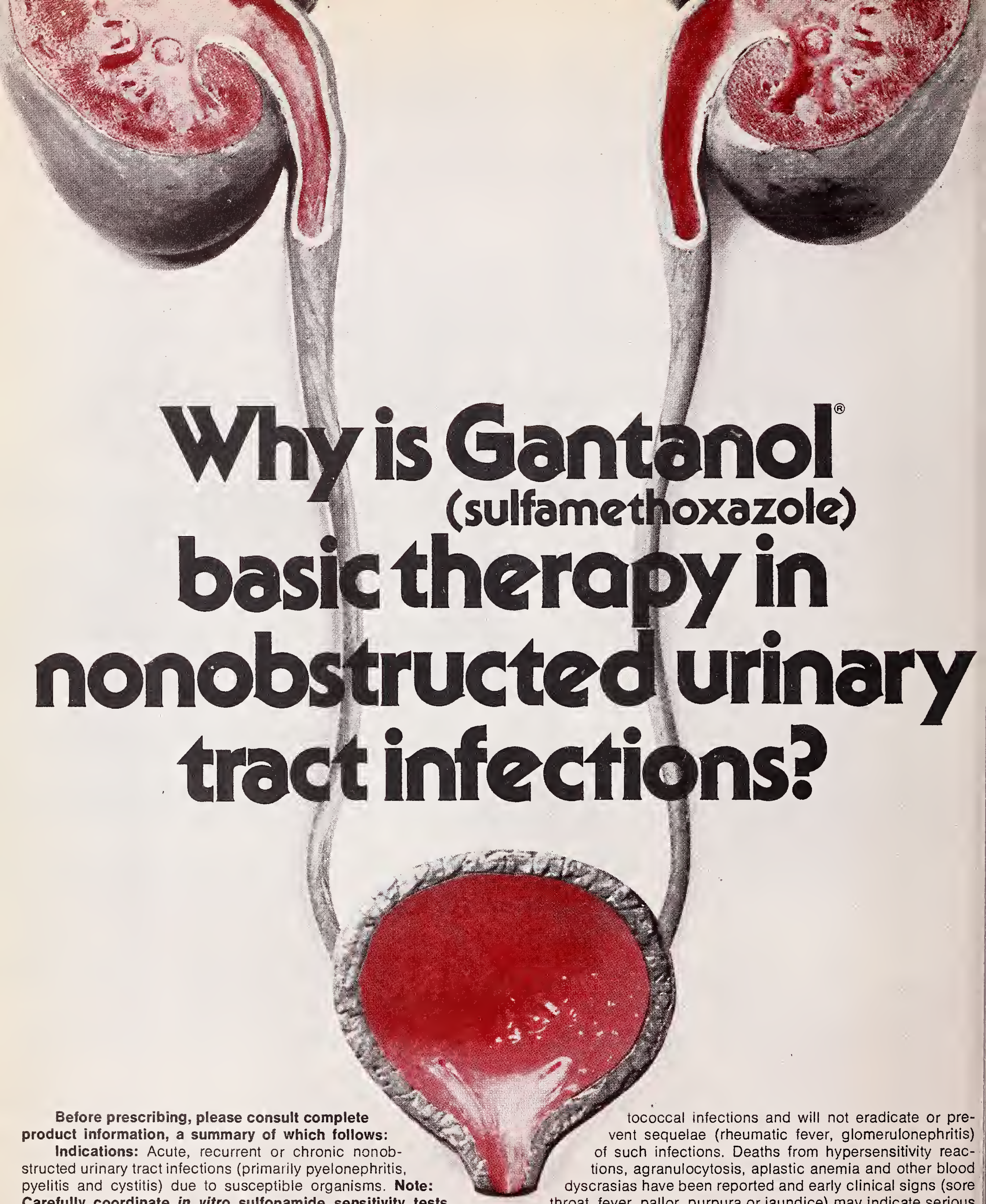
Tisher, Paul W., University of Iowa, 1935. Dr. Tisher was a practicing ophthalmologist in the Hartford area since 1938. He was a former president of the New Britain Medical Society and the Hartford County Medical Society. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Tisher died December 22, 1974, at the age of 65.

CLEAR YOUR MEETING DATES THROUGH CSMS

Society members are urged to take advantage of the CSMS service which maintains a calendar of all major medical meetings in the state.

Far too often, there is a conflict in the dates of these meetings, which involve many of the same medical leaders. It is unfortunate, for instance, when a major county hospital holds a meeting at the same time as an annual meeting of the county Association or the House of Delegates of the State Medical Society.

To avoid these conflicts physicians are asked to call the CSMS office, listing the dates of their meetings and to check to see if any other events have already been scheduled for the same time.



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pura, hypoprothrombinemia and methemoglobinemia); *allergic reactions* (erythema multiforme, skin eruptions, epidermal necrolysis, urticaria, serum sickness, pruritus, exfoliative dermatitis, anaphylactoid reactions, periorbital edema, conjunctival and scleral injection, photosensitization, arthralgia and allergic myocarditis); *gastrointestinal reactions* (nausea, emesis, abdominal pains, hepatitis, diarrhea, anorexia, pancreatitis and stomatitis); *CNS reactions* (headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo and insomnia); *miscellaneous reactions* (drug fever, chills, toxic nephrosis with oliguria and anuria, periarteritis nodosa and L.E. phenomenon). Due to certain chemical similarities with some goitrogens, diuretics (acetazolamide, thiazides) and oral hypoglycemic agents, sulfonamides have caused rare instances of goiter production, diuresis and hypoglycemia as well as thyroid malignancies in rats following long-term administration. Cross-sensitivity with these agents may exist.

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The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiry of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511, (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine.*

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

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Internal Medicine: Fourth board certified internist to join group in eastern Connecticut shore community. Community hospital. Send resume to CSMS.

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Internal Medicine: Board qualified internist to join three man primary care group. Write Charles R. Williams, M.D., 325 Reef Road, Fairfield, Connecticut 06430.

Otolaryngologists: Board qualified ENT associate needed. Serving central Connecticut. Contact: Irving Guttenberg, M.D., 219 West Main Street, Meriden, Connecticut. 06450.

Pediatrician: Part time. Greater New Haven area. Contact: Carlos B. Zilveti, M.D., Director of Maternal and Child Health Dept. of Health, One State Street, New Haven, Connecticut. Tel.: 652-0151, ext. 437 or 438.

Pediatrician: Associate needed in Cheshire area. Send resume to CSMS.

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PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

(If no name is listed, contact the Physicians Placement Service)

Internal Medicine: Board certified. Desires Western Connecticut. Torrington - Danbury area. Group or associate practice. 29 years old. Available mid 1975. Presently in U.S. Navy. Bruce A. Sobin, M.D., 2121 W. Main Road, Portsmouth, Rhode Island 02871.

OB/GYN: St. Louis University School of Medicine graduate wishes associate type practice in large or medium-sized community. Completing residency at Nassau County Medical Center. 30 years old; married. Richard Fox, M.D., 200 Carman Avenue, Apt. 19-B, East Meadow, New York 11554.

Ophthalmology: Presently at Buffalo General, V.A. and Children's Hospital. 28 years old. Married. Solo, group or associate practice in a larger city. Available July 1975. Barry W. Haight, M.D., 112 Cable Street, Kenmore, New York 14223.

Ophthalmology: Will complete residency at Washington Hospital Center, Washington, D.C., in July 1975. Desires group or associate practice. 31 years old. Married. Alan J. Segal, M.D., 9244 Three Oaks Drive, Silver Spring, Maryland 20901.

Ophthalmology: Board eligible. Connecticut license. Presently Retina Fellow at Medical College of Wisconsin. Yale and NYU graduate; Tufts-New England Medical Center. Desires to return to Connecticut. Available July 1975. Robert A. Wiznia, M.D., 2532 N. 124 St., Apt. 247, Wauwatusa, Wisconsin 53226.

Orthopaedic Surgery: Board certified in rheumatology and Board eligible in orthopaedics. Available late spring. Trained at Columbia and Harvard. 30 years old. Desires solo, group or associate type practice in larger community. James E. Elbaor, M.D., 75 St. Alphonsus Street, Boston, Massachusetts 02120.

Orthopaedics: Connecticut license, Board eligible. Available in July 1975. Georgetown Medical, Mt. Sinai and Albert Einstein residency. Presently at Bowman Gray School of Medicine in Winston-Salem, North Carolina. Eric Garver, M.D., 260-D Glendare Dr., Winston-Salem. 29 years old. Married. Desires group or associate practice.

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Orthopaedics: Available July 1975. Presently at University of Rochester. Board eligible. Associate type of practice. 30 years old. Married. Hubert F. Riegler, M.D., 308 University Place, Rochester, New York 14620.

Otolaryngology: Board certified. Connecticut license. Presently in practice. 37 years old. Group or partnership, or solo in community needing ENT coverage. Can be available on short notice. Wishes to return to New England. David J. Langenbrunner, M.D., 103 Turfway Road, Florence, Kentucky 41042.

Otolaryngology: Board certified. Princeton, Pennsylvania Medical. New York University and Bellevue residency. Available with short notice. 30 years old. Married. Wishes to leave N.Y.C. Harvey M. Plasse, M.D., 420 East 55th Street, N.Y.C. 10022.

Otolaryngology: Board certified. Available July 1975. University of Michigan Medical and University of Cincinnati residency. 32 years old. Married. Group or associate practice. Richard A. Weinberg, M.D., 3203 Albin Drive, San Antonio, Texas 78209.

Pathology (AP and CP): Board eligible. Available July 1975. Jefferson Medical College. Community hospital desired. 29 years old. John F. McCormick, M.D., 807 Lombard Street, Philadelphia, Pennsylvania 19147.

Pathology: General Pathology with concentration in CP. Board eligible. Originally from Connecticut and wishes to return. Jeffrey J. Skovronsky, M.D., 2691 Pasadena Avenue, Long Beach, California 90806.

Pediatrics: Board eligible. Interested in pediatric allergy. Available June 1975. 32 years old. Presently in military. Residency at Children's Hospital in Philadelphia. Marc W. Deitch, M.D., 102 Mizner Avenue, Ft. Huachuca, Arizona 85613.

Pediatrics: Board eligible. FLEX. Group or associate or institutional practice desired. 30 years old. Available January 1975. Jerry J. Ferlauto, M.D., 2210 Aubern Street, Rockford, Illinois 61103.

Pediatrics: Board eligible. Presently in the Air Force. Available July 1975. 30 years old. Married. Georgetown Medical School. Residency at Albert Einstein College of Medicine. Desires group or associate or institutional practice. Martin Pinsley, M.D., 4516 Shady Lane, Wichita Falls, Texas 76308.

Pediatrics: Board eligible. Presently in Connecticut completing residency program. Chief resident at Burgdorf Health Center's out-patient department in Hartford. Wishes to remain in Connecticut. 27 years old. Married. John Schreiber, M.D., 6-B Wedgewood Drive, Bloomfield, Connecticut 06002.

Pediatrics: Board eligible. Presently in the U.S. Army. Dartmouth Harvard Medical. Children's Hospital in Boston. 29 years old. Available July 1975. Group practice desired. Edward I. Walkley, M.D., 15 5th Artillery Road, Ft. Leavenworth, Kansas 66027.

Pediatrics: Bridgeport native wishes to return to Connecticut. Presently in Air Force. Available August 1975. Board eligible. Group or associate type practice. Medical College of Virginia. Albert Einstein College of Medicine internship and residency. 30 years old. Gerald D. Weintraub, M.D., 7331 E. Tamara Drive, Tucson, Arizona 85730.

General Surgery: Board eligible. Interested in trauma and in peripheral vascular surgery. Wesleyan grad. Pennsylvania Medical. Presently resident in Ann Arbor, Michigan. 2 years in U.S. Army. 31 years old. Married. Group or associate practice desired. John R. Clarke, M.D., 2746 Page Street, Ann Arbor, Michigan 48104.

General Surgery: Board eligible. Connecticut license. Available July 1975. Connecticut native. N.J. College of Medicine and St. Raphael's-Albany Medical Center residency. 32 years old. Kenneth A. Ciardiello, M.D., 30th Field Hospital, Augsburg, Germany, APO N.Y. 09178.

General Surgery: Board certified. 34 years old. Available August 1975. N.Y.U. Medical. Bronx Municipal Hospital Center. Presently in Air Force. Stephen H. Green, M.D., 6938 Post Street, Edwards Air Force Base, California 93523.

General Surgery and Peripheral Vascular: Available July 1975. Board eligible. Active in upper and lower GI fibreoptic endoscopy. Presently in U.S. Army. Steven P. Kahn, M.D., 9634 Basket Ring Road, Columbia, Maryland 21045.

General Surgery: Group or associate practice. Available July 1975. Presently chief surgical resident. Board eligible. Tufts Medical School; Nassau County Medical Center. 29 years old. Married. Peter Salzer, M.D., 200 Carman Avenue, East Meadow, New York 11554.

General Surgery and Gynecological Surgery: Certified in OB/GYN. Board eligible in general surgery. Tufts Medical School. 44 years old. Married. Prefers group practice. Lawrence J. Phalone, M.D., 12538 Leavenworth Street, Omaha, Nebraska 68154

Thoracic Surgery: General Thoracic and Cardiac surgery. Group or associate practice. Board eligible. 35 years old. New York Medical College, Bellevue and Boston City Hospitals. Jack C. Lee, M.D., 860 Harrison Avenue, Apt. 805, Boston, Massachusetts 02118.

Urology: Board eligible. New Jersey license. 36 years old. Married. M. F. Abidin, M.D., 227 Cambridge Avenue, Jersey City, New Jersey 07307.

Urology: Available July 1975. Native of Waterbury. Ohio State Medical School. Board eligible. Group, solo or associate practice. Harold T. Collins, M.D., 1054 West Chalet Drive, Mobile, Alabama 36608.

Urology: Available July 1975. Board eligible. Associate, group or solo practice. Harvard and University of Vermont Medical School. Joseph M. DeCenzo, M.D., Woodbine Road, Shelburne, Vermont 05482.

Urology: Board eligible. 30 years old. Duke. Cornell-N.Y. Hospital. University Hospital Ann Arbor. Group or associate practice. Stephen A. Koff, M.D., 12260 Stone Drive, Ann Arbor, Michigan 48105.

Urology: Available July 1975. Tufts and Cornell-N.Y. Hospital. 32 years old. Solo, group or associate practice. Harvey A. Koniasberg, M.D., 445 E. 68th Street, New York, N.Y. 10021.

Urology: Board eligible. Solo or associate practice preferred. Yale. Columbia Medical School, Darmouth-Hitchcock Hospital and Medical College of Virginia. 34 years old. Presently in service. Available June 1975.

Urology: Board eligible. 31 years old. Available July 1975. New York and California licenses. Solo or associate practice. Columbia and Downstate Medical. Presently at Montefiore Hospital. Joel W. Goldsmith, M.D., 5700 Arlington Avenue, New York, N.Y. 10471.

Ophthalmology: Board certified. 31 years old. Solo, group or associate practice. Large or medium-sized city. Available July 1975. Presently with U.S. Public Health Service Hospital. Melvyn Damast, M.D., 1351 Bay Street, Apt. 12, Staten Island, New York 10305.

Pediatrics: Board eligible. Group or associate practice. Available July 1975. 29 years old. N.Y.U. Medical. Bellevue and Boston City Hospitals. Melvin I. Katz, M.D., 8 Hallmark Gardens, Burlington, Massachusetts 01803.

Psychiatry: Board eligible. Available July 1975. Group or institutional practice. 30 years old. Presently in the Navy. William A.F. Woods, M.D., 6060 Churchland Blvd., No. 83, Portsmouth, Virginia 23703.

General Medicine: Medium or small community. Available June 1975. Completing 1 year of IM residency. Desires primary care in community needing a physician. Bowdoin, Rochester Medical, University of Texas internship and residency. Allan Currie, M.D., 6523 Spring Well, San Antonio, Texas 78249.

General Internal Medicine: Connecticut license. Board certified. Part or full time. Broad experience. Former solo practitioner. Industrial and teaching experience. Relocating in Connecticut. for semi-retirement. I.A. Schiller, M.D., 74 B. Dakota Lane, Stratford, Connecticut 06497. Tel: 375-0398.

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Connecticut Medicine

The Journal of the Connecticut State Medical Society

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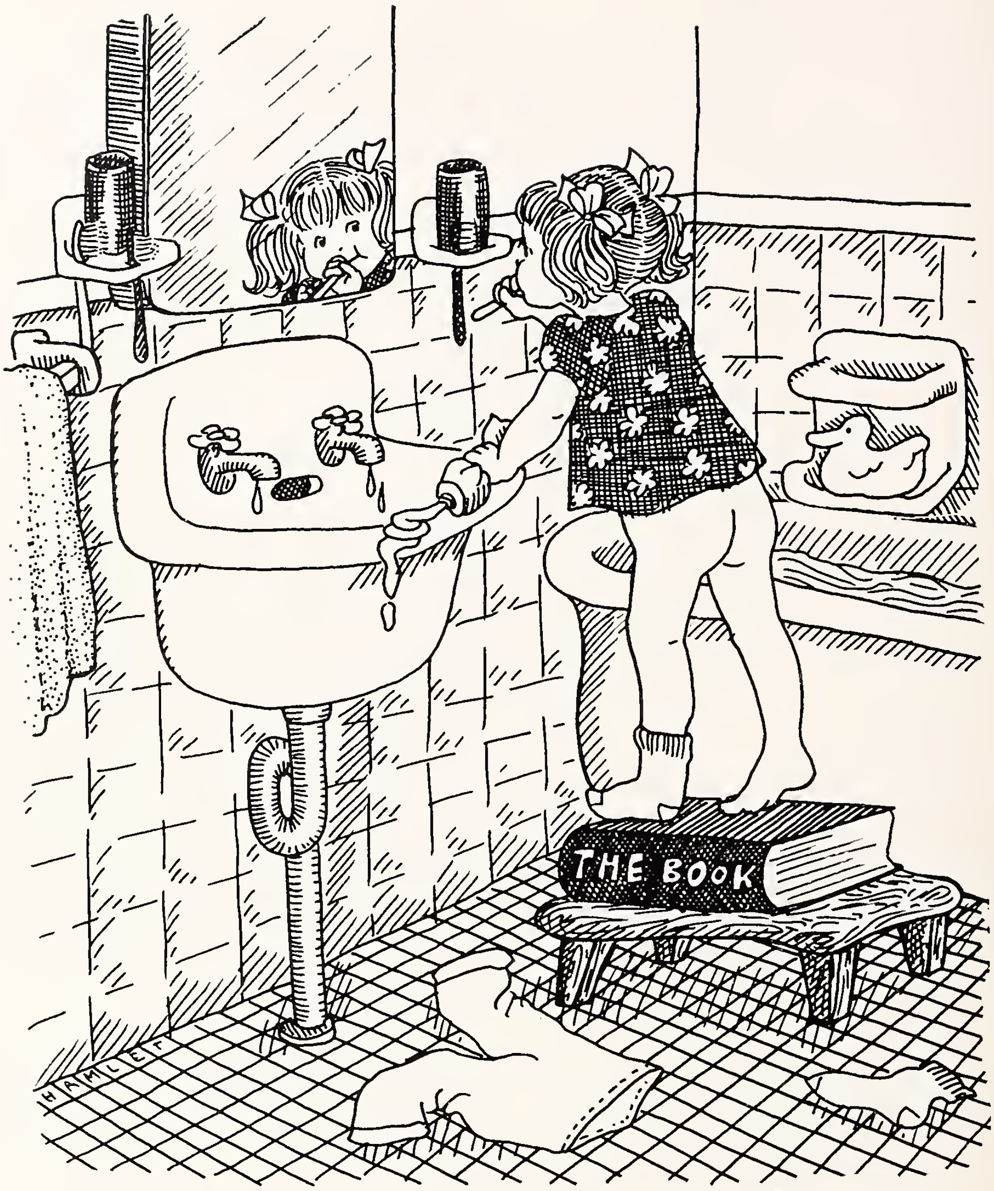

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MARCH, 1975
Vol. 39/No. 3

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Guidelines for the Use of Oral Hypoglycemic Drug Therapy: The Balance of Risks Versus Benefits

Phillip L. Poffenbarger, M.D. and Fred A. White, M.D.

Abstract—The practicing physician is caught between the opposing sides of the debate regarding the use of oral hypoglycemic agents in the management of adult-onset diabetes mellitus. Despite the considerable controversy over the University Group Diabetes Program (UGDP) study, tolbutamide appears to induce an undefined cardiac toxicity in man when administered chronically at a fixed dose of 1.5 gm daily. Phenformin may also induce cardic toxicity when administered chronically at 100 mg daily; however, this latter conclusion is on less firm statistical grounds that the tolbutamide conclusion.

On the basis of pharmacologic considerations of the extrapancreatic effects of other oral hypoglycemic agents it does not seem completely rational to extrapolate the UGDP results to all other antidiabetic drugs. And the observed toxic effects of tolbutamide and phenformin may result from high accrued blood levels or drug-drug interactions particularly when administered chronically in fixed-dose schedules and in combination with other drugs. Clearly additional research is required to answer this question.

The decision regarding pharmacologic therapy of adult-onset diabetes mellitus must weigh these potential risks against the benefits of glucose control. The UGDP has emphasized the failure of diet therapy alone in maintaining normal glucose homeostasis. Insulin therapy, employed wisely, probably represents the best choice by which near normal homeostasis can be achieved. If insulin cannot be employed, the oral hypoglycemic agents represent a second best alternative, but the present state of knowledge is inadequate to formulate ideal guidelines for their use.

DR. PHILLIP L. POFFENBARGER, Associate Professor of Internal Medicine and Human Biological Chemistry; DR. FRED A. WHITE, Clinical Fellow, Division of Endocrinology and Metabolism, The Departments of Internal Medicine and Human Biological Chemistry, University of Texas Medical Branch, Galveston, Texas.

Introduction

> "Disagreement is refreshing when two men desire to compare their views to find out truth. Controversy is wretched when it is only an attempt to prove another wrong. It destroys humble inquiry after truth and throws all energy into an attempt to prove ourselves right—a spirit in which no man gets at truth."
>
> F.W. Robertson, (1816-53)[1]

The furor created by the premature news releases of the results of the University Group Diabetes Program (UGDP) study has not yet completely settled; however, it is both appropriate and necessary to continue to humbly address ourselves to the issues and problems raised by this study. If we ignore the UGDP study results and the controversy, in a vain attempt to gain some measure of self-assurance in our concept of the proper use of oral hypoglycemic drug therapy, then our therapeutic directives may be falsely based. Contrawise, if we consider oral hypoglycemic agents useless and altogether dangerous, then our biochemical and pharmacological notions of the principles of sulfonylurea and biguanide drug action are biased. The middle ground is not easily tread; it is an uncertain ground. Most physicians probably manage their adult-onset diabetic patients within the limits of this uncertain ground; that is, based upon a decade of "positive" experience with the use of oral hypoglycemic agents they continue to prescribe these drugs yet they experience both serious concern and scientific curosity regarding the UGDP controversy.

The purpose of this review is threefold: 1) to provide an analysis of the UGDP controversy, 2) to focus attention on the pharmacology of the oral hypoglycemic agents and 3) to outline therapeutic guidelines for their use based upon the UGDP study and more recent work.

The UGDP Controversy Revisited

The UGDP study was begun in February 1961. It was a multi-centered prospective study to determine the effect of blood glucose control on the development of vascular complications in adult-onset diabetes mellitus and to ascertain the natural course of the disease. A total of 823 diabetic patients of both sexes with a mean age of 52.7 years were enrolled and randomly distributed into four study groups initially. The overall mean fasting blood glucose for these patients at the time of entry into the UGDP study was 143 ∓ 58.6 mg% (SD); the mean two hour post-glucose load blood sugar was 229 ∓ 82.5 mg%. The four study groups included a placebo group (205 patients), a fixed dose (1500 mg per day) tolbutamide group (204 patients), a fixed dose (10 to 16 units of U-80 Lente per day based upon body surface area) insulin group (210 patients), and a variable dose insulin group (204 patients). In this latter group, U-80 Lente was administered in an attempt to maintain normal glucose control.[1]

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[1] *Frederick W. Robertson was a popular English clergyman, better known for his ministry at Trinity Chapel, Brighton, which resulted in several published works of his lectures and sermons.*

In the fourth year of the study increased cardiovascular mortality began to appear in the tolbutamide treated group; by the sixth year ten cardiovascular deaths had occurred in the placebo group, 26 in the tolbutamide group, 13 in the fixed insulin group, and 12 in the variable insulin group. This increased cardiovascular mortality in the tolbutamide group was significantly greater than the other groups, and it was considered necessary by the UGDP to discontinue use of tolbutamide in the study.[1]

Approximately 18 months after institution of this study a fixed-dose phenformin group (100 mg DBI-TD; 50 mg before breakfast, 50 mg before the evening meal) was added by recruitment of patients from 6 of the 12 study centers. Again, by the sixth year of prospective follow-up study 26 cardiovascular deaths had occurred in the phenformin treated group of 204 patients.[2] Although the late entry of this group created a "two-pool" statistical design problem,[2 3 4 5] these deaths were again significantly greater than that which occurred in placebo, fixed-insulin, and variable-insulin treated groups.[2]

Detailed results of the UGDP study and several independent statistical appraisals have been published[1 6] and subjected to intense public debate. Generally, two polarized camps have characterized this debate. In one camp are those physicians who believe the UGDP study is invalid and should not influence our previously accepted guidelines for the clinical use of oral hypoglycemic drugs. In the opposite camp reside those who believe strict curtailment of the use of oral hypoglycemic drugs is warranted. Consultants to The Medical Letter On Drugs and Therapeutics characterize this position by stating " . . . . there is no justification for the use of tolbutamide or other oral agents solely to lower blood sugar in such patients (adult-onset diabetics), especially in view of the increased cardiovascular mortality that may be associated with their use."[7] In the midst of these two camps are the great majority of practicing physicians caring for an estimated three million adult-onset diabetics who receive one or more of the oral antidiabetic medications.[8]

It seems clear that this issue will not be completely settled by more public debate or by additional statistical appraisal of the UGDP study, and it seems unwise to place the burden of therapeutic choice on the physician without a careful weighing of the balance of "risks versus benefits." In order to accomplish this the criticisms and merits of the UGDP study must be summarized and the pharmacology of the oral hypoglycemic agents must be surveyed.

Significant Criticisms and Merits of the UGDP Study

Criticism has been frequently voiced regarding the patient selection process of the UGDP study, and more seriously, regarding the unavailability of or failure to obtain certain baseline characteristics that might indicate or help predict cardiovascular risk.[3 5 9 10] However, one of the most powerful aspects of the UGDP study design was the randomization of patients into the respective study groups. The errors of omission in acquiring baseline data were, therefore, randomized to all study groups; it is unlikely that these errors of omission significantly biased any single group. Patient selection criteria was altered after the initial few months of the study and it was subsequently learned that 69 patients (randomized into the initial four study groups) did not completely fulfill the diagnostic criteria of a summated oral glucose tolerance test value of greater than 500. Critics of the UGDP site this error as a bias of the study; however, in fact, the UGDP decided to leave these 69 patients in the study in order to not bias the results.[5 11] Subsequently, it has been shown that mortality differences for the tolbutamide group would have been magnified more had these patients been deleted from the final analysis.[11]

In spite of the patient randomizing process, another criticism frequently raised is that the tolbutamide treated group exhibited a higher proportion of cardiovascular risk factors upon entry into the study. This is, in fact, not the case.[1 2 6] This potential problem was scrutinized by several independent statisticians and, more recently, re-analyzed by the UGDP group.[6] In this re-analysis, excess cardiovascular mortality was still found in the tolbutamide treated group when all subjects with any cardiovascular risk factor at the time of entry into the study were selectively removed from the statistical analysis. This finding essentially puts to rest the arguments of unequal risks among the study groups and underscores the validity of the mortality results.

Several critics of the UGDP have pointed out problems in the study protocol that they consider invalidating. The two major issues in this aspect of the debate are the decision to administer tolbutamide in a 1500 mg per day fixed dose and the "late" decision to include a phenformin treated group.

The UGDP considers that a fixed dose of tolbutamide, as opposed to the more usual clinical situation of a variable dose of tolbutamide, could not explain the increased cardiovascular mortality observed in this study group.[11] This debate is actually rather vague with weak aspects on both sides. For one, while it is common practice to begin diabetics on a low dose of tolbutamide and subsequently increase the dose as hyperglycemia in the patient may dictate, it has also been common to find patients on 1500 to 2000 mg of tolbutamide per day without normalization of the fasting blood glucose.

Perhaps the more important consideration of the fixed tolbutamide dose issue, that is not discussed by the UGDP, is the accrued blood level of the drug on a fixed dose schedule. In man, tolbutamide is carboxylated by the liver and subsequently excreted by the kidney. The carboxylated product is not active in promoting insulin secretion, but little information is published about potential extra-pancreatic effects.[12] In addition, wide variation in individual rates of drug metabolism are clearly documented[13] and it is possible that a significant portion of the tolbutamide treated group accrued exceptionally high blood levels of the drug in the face of an unresponsive pancreas. Finally, drug-drug interactions are also well known for tolbutamide,[14] causing prolongation of its half-life in blood yet we know little of the drugs the patients received in the UGDP study.[1] In short, cardiovascular toxicity may be a combination of cardiac susceptibility to chronically elevated blood levels of tolbutamide or its carboxylated by-product, and drug-drug interactions either displacing tolbutamide from albumin, its carrier protein in plasma,[15] or acting in concert at the level of the myocardium. These areas of sulfonylurea pharmacology certainly merit further scrutiny and study.

The late entry of the phenformin treated group was decided upon by the UGDP because of its rising popularity in the management of the adult-onset diabetic and its recent release to the market by the FDA.[2] The statistical problem created by this alteration in the study protocol has been dealt with admirably by the UGDP,[2] and independent statistical review has both supported[4 5] and negated[3] the handling of the results. It should be made clear, however, that this controversy does not alter the analysis of the original four study groups, since each of the 12 cooperating study centers contributed equally to these groups.

Most physicians treating the obese mild diabetic have observed that phenformin therapy, either alone or in combination with a sulfonylurea or insulin, does assist in achieving normalization of blood glucose. The mechanism of action of phenformin is complex, but it appears that its major effect is to inhibit hepatic gluconeogenesis, thus decreasing hepatic glucose production.[16] This effect is closely intertwined with the propensity of phenformin treated patients to develop lactic acid excess in the blood since lactate uptake by liver not only provides gluconeogenic substrate but also serves as a route of elimination of metabolically generated hydrogen ion. This result of phenformin action is, of course worrisome. Lactic acidosis can be difficult to manage; however, this problem appears to be largely dose dependent and much more likely to occur on phenformin regimes exceeding 100 mg per day. In this regard, one patient in the UGDP phenformin study group died from lactic acidosis.[2] In the insulin insensitive obese diabetic, then, phenformin action assists in lowering blood glucose where insulin action may fail. Hypoglycemia from phenformin therapy alone is virtually unknown, except in rare instances of suicidal overdose.

The therapeutic issues with phenformin, raised by the mortality results of the UGDP study, are not unlike those for tolbutamide, and currently we are faced with the same dilemma when deciding upon an appropriate therapeutic course of action for the diabetic. The statistical analysis debate is more intense here. The pharmacologic rationale for using phenformin appears reasonably sound, yet the UGDP study results indicate an enhanced rate of cardiovascular death with long term use of the drug. The balance of risks versus benefits may weigh in favor of continued use of phenformin, especially if the dose does not exceed 50 to 100 mg per day; however, the final decision at the moment depends also, in part, on the now classic debate of strict versus lenient control of blood glucose.

The UGDP study was probably not well suited to answer the controversial question concerning strict versus lenient blood glucose control in the management of adult-onset diabetes mellitus; however, the study has concluded that no beneficial therapeutic effect was found when the five study groups were compared.[6] Several persuasive reasons exist for accepting this conclusion with reservation. First, it is generally accepted that mild glucose intolerance may exist asymptomatically for years before diagnosis is made; therefore, the patients enrolled in the UGDP study may well have had mild diabetes of long duration. In this regard it would be helpful to know the obstetric history of the women enrolled in the study, especially since 733 of the 1,027 total patients were female.[1] The problem here is that it may be impossible to observe a difference in treatment groups when studying them for only six years. Second, blood glucose control was not realized, in large part, in the study groups. By the sixth year of the study the mean fasting blood glucose values were: placebo group, 157 mg%; tolbutamide group, 154 mg%; insulin standard dose group, 148 mg% and insulin variable group, 116 mg%. The comparable one hour postprandial values were: placebo, 252 mg%; tolbutamide, 240 mg%; insulin standard, 250 mg%; and insulin variable, 218 mg%.[6] Furthermore, throughout the study 73% of the placebo group were considered to be in fair to poor control as were 62% of the tolbutamide group, 61% of the insulin standard group and 51% of the insulin variable group. Clearly, the lesson learned here is not only that blood glucose normalization is difficult to achieve in the diabetic population, but also that it is difficult to make predictions of the clinical efficacy of glucose control when the majority of patients in the study are not controlled. The weak aspect of this reasoning resides in the fact that the insulin variable group did achieve better glucose control (but not normalization) especially when considering the overnite fasting blood glucose data; nevertheless, there were no beneficial effects found in this group.

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The entire debate over strict versus lenient blood glucose control is, in fact, at times naive. There are numerous factors besides the level of blood glucose alone that determine the outcome of diabetic complications. This is not to imply blood glucose level is not important but is to recognize the pathological consequences of hypertension, hypercholesterolemia, hypertriglyceridemia, the frequency and severity of infections and acidotic states, exposure to drugs, toxins, and other as yet poorly defined endogenous or genetic factors.

The importance of blood glucose control alone is not easily debated from the available clinical information. In fact, the UGDP study has taught us, as have studies of continuous monitoring of blood glucose, that normal blood glucose homeostasis is difficult to achieve in the diabetic by exogenous pharmacologic means. The debate favoring an earnest attempt to achieve normalization of blood glucose, however, is strengthened by considerations of basic research data. These may be briefly summarized as follows:

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1. Phylogenetic considerations of blood glucose homeostasis in vertebrates lead to the conclusion that normally glucose levels are regulated within narrow limits in most animal species. The usual ranges found vary from 40-100 mg/100 ml. Some birds exhibit higher regulated levels, varying from 120-180 mg/100 ml. Another exception appears to be arctic fish that vary their blood glucose inversely with ambient water temperature; the lower the water temperature the higher the glucose level. Values as high as 1000 mg% have been observed and may serve the function of a biological antifreeze. Normal man appears to regulate blood glucose between 50 and 100 mg/100 ml. In healthy young adults it is common to observe a "flat" oral glucose tolerance curve, especially if simple ambulatory activity is allowed during the test.

2. General considerations of the homeostasis of other metabolic fuels also reveals that animals regulate amino acids and free fatty acids within narrowly defined ranges. Certain inborn errors of metabolism (phenylketonuria) are excellent examples of the pathological consequences of elevated levels of amino acids, and elevated levels of free fatty acids, such as may occur following excess caffeine ingestion, may lead to enhanced hepatic biosynthesis and secretion of very low density lipoprotein (VLDL) and ultimately atherosclerosis. These general concepts do not support a relaxed attitude towards blood glucose control. An elaborate control system has evolved in the animal kingdom to provide maintenance of metabolic fuel homeostasis within narrowly defined ranges, and the pathological consequences of disturbances in this system are becoming more apparent.

3. Chronic hyperglycemia may deplete pancreatic beta cell mass and impair beta cell replicative potential. The basic evidence for this statement is not proven, nor is it well founded in fact, but several observations are supportive. Firstly, chronic hyperglycemia in dogs produced by growth hormone administration can lead to permanent diabetes mellitus. In man, the incidence of diabetes mellitus in acromegaly approximates 25-60% and is variably reversed by elimination of the growth hormone excess. Similarly, it is common to observe a so-called "honeymoon period" following institution of diet and/or drug therapy in newly diagnosed diabetes. This period is characterized by partial and sometimes nearly complete recovery of beta cell function following several weeks of blood glucose control. It is extremely difficult to study this process, but the evidence suggests that chronic hyperglycemia may impair beta cell function and replicative potential.

4. Hyperglycemia may interfere with host-defense mechanisms. This issue has been studied more extensively. Humoral and tissue immune mechanisms do not appear to be impaired, but leukocyte motility and phagocytic activity are significantly inhibited at glucose levels of 250 mg/100 ml or more. At 150-200 mg/100 ml only slight impairment has been found. Wound healing has surprisingly not been well studied and moderate hyperglycemia (150-250 mg/100 ml) without vascular insufficiency may not greatly impair tissue repair processes.

5. Moderate hyperglycemia will result in sorbitol accumulation in most tissues that are dependent solely on the level of extracellular glucose concentration for regulation of glucose uptake. This includes insulin insensitive tissues such as the ocular lens, brain and peripheral nerve, renal medulla, and vascular wall structures. These tissues may metabolize glucose by way of the polyol pathway, particularly at high ambient glucose levels, in addition to the pathways of glycolysis, glycogenesis, direct oxidative pathway (HMP-shunt) and the complete oxidative pathway of the Krebs cycle. Sorbitol accumulation intracellularly can predispose to pathological consequences, such as cataract formation in the lens. Although the precise role of hyperglycemia alone and the polyol pathway is not yet defined for renal papillary necrosis, neuropathy, retinopathy, and vascular wall damage, the evidence to date compels one to consider hyperglycemia potentially damaging to insulin insensitive tissues.

6. Basement membrane thickening has been observed in both man and animal models with inherited and acquired varieties of diabetes mellitus. The structural pathology resides in excessive carbohydration of the basement membrane glycoprotein; the unique feature of this process is that glucose and galactose exist as a disaccharide unit linked to the protein moiety of the glycoprotein. Glucose is not found in other glycoproteins. It is attached to the basement membrane protein after assembly of the protein at the ribosome; that is, the disaccharide unit is attached as a post-ribosomal, non-coded step. It is therefore plausible to visualize epigenetic influence in this process, such as chronic hyperglycemia might produce. Indeed, in the alloxan diabetic rat, hyperglycemia and insulin insufficiency have been associated with elevated activity of the kidney enzymes responsible for placement of glucose onto the disaccharide unit of the basement membrane. Furthermore, studies in man have shown an increase in the number of glucose-galactose disaccharide units attached to diabetic glomerular basement membrane. The presumption presently is that this excess carbohydration may interfere with cross-linking of this protein, rendering it more permeable to macromolecules (nephrotic syndrome) and possibly interfering with degradation (thickening?). Much needs to be studied in this difficult area of biochemistry, but the balance of evidence suggests that glucose levels may epigenetically modulate basement membrane structure and turnover.

To summarize the brief outlines above, the issue of lenient versus strict management of blood glucose control is certainly not settled; furthermore, the UGDP study does not clinically support that glucose control is either beneficial or practical. Nonetheless, basic research efforts and phylogenetic considerations provide several compelling reasons to keep the attainment of normal glucose homeostasis as a rational goal of management and research.

Finally, the issue of cardiotoxicity of all sulfonylureas must be raised since the FDA, the AMA Council on Drugs, and the American Diabetes Association have concluded that the UGDP study results implicate all sulfonylureas as potentially toxic in this respect.[17] [18] This decision is supported by the fact that these agents are structurally similar (Figure 1); however, the side chain (R 2) of the parent molecule may play the determining pharmacologic role in several extra-pancreatic effects. With regard to most tissues, including pancreatic islets and myocardium, it appears that all sulfonylureas inhibit adenosine 3′,5′-cyclic monophosphate phosphodiesterase, one of the enzymes responsible for

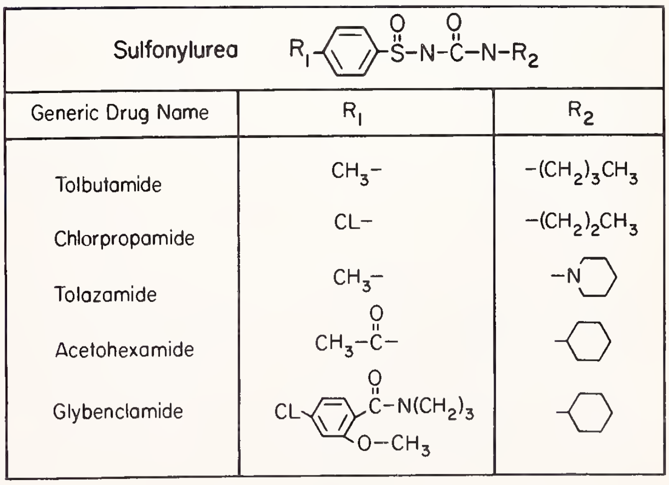

Figure 1

Structural formulae of the sulfonylurea drugs. Trade names are: Orinase (tolbutamide), Diabenase (chlorpropamide), Tolinase (tolazamide), and Dymelor (acetohexamide). Glybenclamide is not yet marketed in the United States. These structural differences markedly influence drug metabolism and excretion, and may also affect the degree of extrapancreatic toxicity seen.

degradation of cyclic AMP.[19] [20] [21] [22] Since catecholamines increase c AMP one would predict that sulfonylureas should potentiate catecholamine effects on the heart; to date this has not been found and we must conclude that the mechanism for tolbutamide cardiotoxicity remains unclear.[21] Of interest in this regard is the recent demonstration that several sulfonylureas affect glycosaminoglycan biosynthesis in vascular tissue.[23]

With respect to other extrapancreatic effects, interesting differences among the sulfonylurea class of drugs are already known. Acetohexamide, for example, is a potent uricosuric agent whereas the other sulfonylureas have no uricosuric action.[24] Finally, tolbutamide and chlorpropamide exert antidiuretic action by inhibiting renal tubular cell adenosine 3',5'-cyclic monophosphate phosphodiesterase, thus potentiating the effect of vasopression which is to crease c AMP. However, glyburide, acetohexamide and tolazamide clearly enhance water excretion.[25] We must, conclude therefore, that extrapancreatic effects of the various sulfonylureas may vary widely and that at the present stage of our knowledge it is not possible to extrapolate cardiotoxicity to all sulfonylureas.

Conclusions

1. It is not possible to outline rigid guidelines for the use of oral hypoglycemic agents in the management of adult-onset diabetes mellitus. The demonstration by the UGDP study of possible cardiotoxicity resulting from the long-term use of a fixed-dose of tolbutamide or phenformin should temper enthusiastic use of these agents.
2. Based upon present pharmacological evidence it is not entirely justifiable to extrapolate possible cardiotoxicity to all oral hypoglycemic agents. Extrapancreatic effects of sulfonylureas are known to differ.
3. The UGDP study fails, for the most part, to answer the question of strict versus lenient blood glucose control since normalization of blood glucose was not achieved. In addition, the time scale of the study was probably not sufficient to study this complex controversial question. Perhaps the more significant lesson learned from the UGDP results is that normalization of glucose homeostasis is very difficult to achieve; however, consideration of several lines of evidence from the basic research laboratory presently support the hypothesis that hyperglycemia can inflict pathological consequences.
4. The therapeutic approach to the diabetic patient, with respect to hyperglycemia, should be to normalize glucose homeostasis insofar as possible. Judicious employment of diet and insulin therapy are the best first line of therapy. In those individuals not controlled on diet and who cannot take insulin, one of the oral hypoglycemic agents is indicated. In this latter situation the physician must weigh the risk of the oral agent against the benefit of achieving improved glucose levels. At the present state of our knowledge, it is not possible to easily balance these factors. Nonetheless, the use of one of the oral agents with full recognition of its major route of degradation, interaction with other drugs, and proper dosage levels, appears rational. If glucose homeostasis is not achieved with the oral agent, it should be discontinued to avoid the potential hazards of extrapancreatic effects.

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Respiratory Failure After Tracheal Reconstruction: A Hopeful Note

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ABSTRACT—**Necessity for assisted or controlled ventilation, following tracheal reconstruction for tracheal stenosis, has been almost tantamount to a death sentence for the patient involved. With meticulous attention to details of ventilatory management, survival can be achieved, as illustrated here.**

Increasing sophistication in the diagnosis and treatment of acute pulmonary insufficiency has produced an increasing number of survivors of prolonged ventilatory support. These survivors have experienced a variety of iatrogenic problems, previously unknown or considered rarities, which in a sense have constituted part of the price of surviving. As with many critical medical problems in the past, the problem of mortality in acute ventilatory failure is gradually being replaced by the problem of morbidity.

One major problem after prolonged ventilatory assistance or control has been tracheal stenosis. The usual location of stenosis has been at the site of the balloon cuffs of endotracheal or tracheostomy tubes, where pressure can produce ischemic tracheal necrosis circumferentially. The other less common site of stenosis is at the stoma of a tracheostomy.

Augmented clinical awareness of this entity has led to prospective efforts in defining its incidence. A recent report by Andrews and Pearson[1] indicated an incidence of tracheal stenosis in 17.5 per cent of patients who required the use of cuffed endotracheal or tracheostomy tubes, in a prospective analysis. Grillo[2] has also reported an incidence of 17 per cent in ventilator patients.

The only acceptable, permanent solution to post-intubation tracheal stenosis developed to date is definitive resection of the stenotic segment with tracheal reconstruction by primary end-to-end anastomosis.

While substantial progress has been made in the recognition and treatment of the patient with post-intubation tracheal stenosis, continuing respiratory insufficiency has been considered a contraindication to tracheal reconstruction, and indeed the use of a ventilator following such reconstruction has proved extremely hazardous.

We were recently confronted with a victim of severe trauma in whom respiratory insufficiency, requiring prolonged ventilatory control by a respirator, occurred following tracheal reconstruction. The successful management of the patient prompted this report.

CASE REPORT

A 39-year-old white female, was brought to the Emergency Room of the Stamford Hospital following a high speed auto accident in which she was the front seat passenger when the car struck a telephone pole.

Her past history was of note in that she had smoked two to three packages of cigarettes daily for many years. She drank substantially as well.

She was conscious but was agitated and incoherent and had an alcoholic breath. Her pulse was 112, and her blood pressure was 90/70 mm. Hg. Positive physical findings included multiple, extensive facial lacerations; an open fracture of the right elbow; splinting and decreased breath sounds in the right chest; absent bowel sounds; guarding and spasm of the lower abdomen; and an unstable pelvis. Diagnostic paracentesis was non-productive.

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Resuscitation was accomplished by the surgical resident staff. X-rays revealed a comminuted fracture of the right elbow, fracture of the surgical neck of the right humerus, multiple right rib fractures, multiple pelvic and sacral fractures, and a fracture of the fifth lumbar vertebrum. Intravenous pyelogram showed perinephric and perivesical hematomas and probably intrarenal hemorrhage.

Following stabilization of vital signs, repair of the soft tissue injuries, and splinting of the fractures, she was transferred to the Intensive Care Unit. She remained relatively stable for the next 24 hours, at which time she convulsed, responding to diphenylhydantoin, diazepam, and paraldehyde. Mental confusion persisted.

Arterial blood gases were satisfactory until the third hospital day when, because of a falling arterial oxygen concentration, a tracheostomy was performed. Assisted ventilation was initiated, using a cuffed tracheostomy tube with a volume-cycled respirator. Regular deflation of the tracheostomy tube cuff for five minutes of every hour was performed.

Because of the need for continuing blood transfusion during four hospital days, without an overt source of blood loss, an intraperitoneal saline lavage was performed. Non-clotting blood was returned. Due to the likelihood that her hemorrhage arose only from her pelvic fractures, and hoping to avoid a high-risk laparotomy, it was elected to apply the G-suit.[3] This device was inflated from ankles to costal margin to obtain pelvic and abdominal compression. With this maneuver, the patient's hemodynamic status stabilized.

Deterioration in her ventilatory status supervened. In spite of normal central venous pressure, the lungs became moist, and chest films showed pulmonary edema. Digoxin and furosemide, as well as large doses of corticosteroids, were given intravenously. These measures failed to induce improvement. Accordingly, the patient was curarized, and controlled ventilation was instituted, with positive end-expiratory pressure of 10 cm. of water. For the next six days, while she remained on constant positive pressure breathing with 100% oxygen, her arterial oxygen concentrations ranged only between 30 and 40 mm. Hg. Thereafter, gradual improvement was observed, allowing reduction of the inspired oxygen content and discontinuation of constant positive pressure breathing. Her pulmonary edema began to clear, clinically and radiographically, unveiling a left lower lobe pneumonia. Tracheal secretions grew out Pseudomonas, which responded to gentamycin.

After two weeks of continuous use of the ventilator, intermittent use was begun. With successful weaning accomplished, removal of the tracheostomy was possible.

The patient continued to exhibit gratifying general improvement. Her mentation and sensorium were normal, and she began to ambulate.

Three weeks following her extubation, just prior to planned discharge from the hospital, the patient developed a constant, non-productive cough. Auscultation of the lungs revealed fine wheezes, and she was placed on bronchodilators. On the following day the wheezes became more prominent, and intercostal retractions were noted. Tracheal stenosis was considered at this time, and emergency tomography demonstrated severe tracheal narrowing to a caliber of 3mm. in the area of the tracheostomy tube cuff. The lumen at the site of the tracheostomy was of normal caliber. The patient's ventilatory status deteriorated rapidly. It became clear that the only realistic hope for her survival lay in emergency tracheal reconstruction.

Bronchoscopy immediately prior to operation confirmed the stenosis seen on X-ray. Through a low collar incision the stenotic area was readily identified just caudal to the thoracic inlet. A resection of 1.5 cm. of trachea was performed followed by end-to-end tracheal anastomosis, using interrupted fine Dacron sutures. The procedure was uneventful from a technical point of view; however, the endotracheal tube could not be removed post-operatively because of the patient's inability to ventilate.

Extubation was attempted the following morning, but the patient rapidly became pulseless and cyanotic and experienced a brief but dramatic bout of ventricular fibrillation. Re-intubation with a small caliber nasotracheal tube was performed. Profound hypoxemia necessitated continued intubation across the tracheal anastomosis, with ventilator support, for the next ten days. During this period the endotracheal tube cuff was not inflated. With slow but continuous improvement in lung function, extubation was finally possible. Repeat tomograms taken at discharge 19 days following the reconstruction showed a normal tracheal caliber. Readmission was required on two subsequent occasions for cauterization of granulation tissue at the tracheal anastomotic site. The patient has since had no further evidence of tracheal impairment. She has now been followed for over two years since tracheal reconstruction.

Discussion

Since the substantial hazard of tracheal stenosis after respiratory support by mechanical ventilators became apparent, efforts have been directed at prevention of the problem. The aim has been to develop cuffs for endotracheal and tracheostomy tubes which would conform to the configuration of the tracheal lumen without exerting harmful pressure effects. Unfortunately, these efforts have not yet eradicated the difficulty, and any patient who has required tracheal intubation with a cuffed tube for more than twenty-four hours should be considered a potential victim of this complication. Any respiratory symptoms in such a patient, ranging from a persistent cough or wheeze to full-blown stridor, represent tracheal stenosis until proven otherwise. Immediate diagnostic studies, including tracheal tomography and contrast tracheography, should be undertaken. Once the diagnosis is made, bougienage may serve as a temporizing measure, but definitive therapy consists of resection and end-to-end anastomosis.

Special problems arise in the patient with preexisting chronic pulmonary disease or in whom there has been recent respiratory failure, both of which were present in our case. In such instances a substantial risk of recurrent respiratory insufficiency after tracheal reconstruction can be anticipated. Transanastomotic intubation following tracheal reconstruction may be essential for ventilatory support. Provided the tube is of small caliber and an inflated cuff is not used, a successful outcome is possible; a team with a high degree of expertise in respiratory care is indispensable in these circumstances. On the other hand, we feel that the patient requiring ventilator support, who develops tracheal stenosis while the ventilator continues to be imperative for survival, is not a candidate for tracheal reconstruction.

To our knowledge, no previously reported patient has survived respiratory failure and prolonged endotracheal intubation of this duration following tracheal reconstruction.

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Chromosome Analysis in Clinical Medicine

Ill Lyong Yoon, M.D.

History

For many years, the human nucleus was believed to contain a diploid number of 48 chromosomes: 23 paired autosomes and 1 pair of sex chromosomes. This number was obtained by studying gonadal and other tissue with rather crude analytical methods which consisted of staining sliced and fixed or squashed preparations with intravital dyes. In man, the large number of chromosomes, their small size, and their tendency to clump made counting a formidable task. It is thus understandable why the erroneous diploid number of 48 chromosomes stood as an established fact for decades.

A major advance in methodology was made independently by Hsu and Hughes in 1952. These investigators working with tissue culture found that the addition of hypotonic solution to growing cells before fixation causes cells to swell by osmotic inhibition and promotes spacial separation of metaphase chromosomes. This greatly facilitated the counting and identification of chromosomes in squashed preparations.

Another outstanding contribution to the technique of chromosome analysis was the addition of colchicine to the culture medium. Colchicine or its analogue diacetylmethyl colchicine (Colcemide) arrests mitoses at metaphase stage by inhibition of spindle formation. It also was found to promote contraction and widening of the chromosomes, thus minimizing overlapping and making the centromere location more prominent. Incubation of chromosome culture with colchicine for 2 - 4 hours before fixation provided many more mitoses to choose from to count number of chromosomes and select for karyotyping.

In 1956, Tjio and Levan, applying these newly developed techniques, were able to demonstrate conclusively that nuclei of cultured human embryonic lung fibroblasts contained a diploid number of 46 chromosomes; 22 pairs of autosomes and 1 pair of sex chromosomes (Fig. I and II). This diploid number has been amply confirmed by many investigators in a wide variety of human tissue.[2]

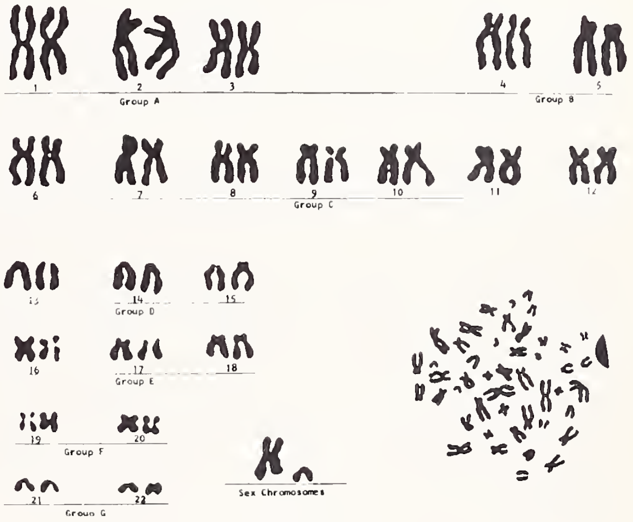

Figure 1

Normal male karyotype showing 22 pairs of autosomes and XY sex chromosomes and metaphase spread of chromosomes (peripheral blood).

In 1959, comparatively simple, rapid and reliable method for chromosome analysis was developed by culturing leukocytes obtained from peripheral blood. Normally these blood cells do not undergo mitotic activity in circulation nor do they do so in vitro. It was learned that red kidney bean extract, phytohemagglutinin (PHA), in the culture system stimulates the cell division of mononuclear cells, where phytohemagglutinin, a mucoprotein is added to a heparinized blood specimen, many leucocytes, primarily lymphocytes will enter mitosis (undergo blastic transformation) in culture.

The mechanism by which PHA initiates mitotic activity in leucocytes is not well understood at present. Mitogenic activity is not only manifest by PHA but also by tuberculin and leucocyte antisera. This has suggested that PHA may exert its mitogenic

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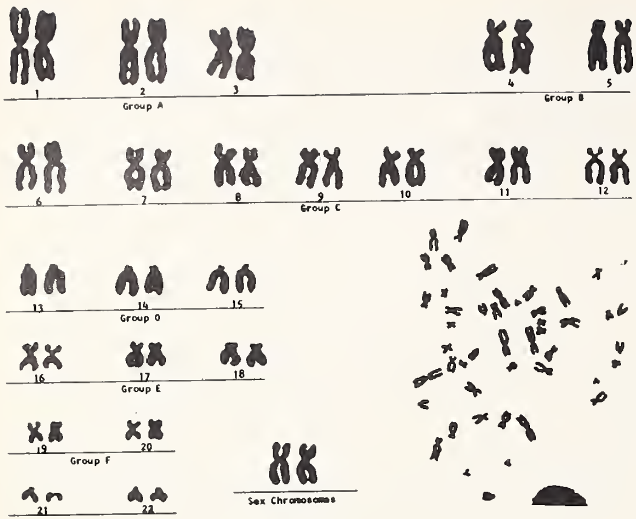

Figure 2

Normal female karyotype showing 22 autosomes and XX set chromosomes and metaphase spread of chromosomes (peripheral blood).

activity on an immunological basis by acting as an antigen to stimulate proliferation of lymphoid cells to produce antibody.

With the better technique, investigators began studies of pathological conditions, and LeJeune et al.[3] first discovered that cases of Down's syndrome (mongoloids) had one extra small acrocentric chromosone (Fig. III). This was the beginning of chromosome analysis in clinical medicine. Since then many conditions are found to be due to chromosome defect, such as Klinefelter's Syndrome, Turner's Syndrome and it was found that most Down's cases with 47 chromosomes (G Trisomy) are non-hereditary.

Technique

Peripheral blood is most commonly used.[4 5] Only a few c.c. of blood are drawn in a previously heparinized syringe and about 10 drops of whole blood (plasma can also be used) are inoculated into TC 199 tissue culture media, with phytohemagglutinin[6] (red kidney bean extract). Phytohemagglutinin stimulates mature lymphocytes to divide. The culture is then incubated at 37 degrees Centigrade for 58-72 hours. Mitoses are harvested at metaphase with the addition of Colchicine.[2 7]

The cells are then treated with hypotonic KCL[1 2 7] solution and fixed with alcohol-acetic acid solution. In hypotonic solution, the cells become distended and chromosomes separate from one another. Following centrifugation, the cells are spread on a glass slide, then smears are heat treated by igniting to rupture the cell membrane and spread chromosomes in metaphase and some smears are air dried for banding technique.[8] A total of 25 such metaphases are routinely counted under the microscope in our laboratory and chromosome numbers are determined (modal number). Several of these metaphases are photographed with high contrast black and white film and developed in the usual fashion. These photographs are then enlarged to 8″ x 10″ and individual chromosomes are cut, and the karyotype is then prepared by arranging individual chromosomes according to their size and the location of the centromere (a point where short and long arms join).[9 10 11 12] Group C and G are most difficult to distinguish from sex chromosomes X and Y respectively, and the tritiated thymidine technique[13] has been used to assist in identification. This technique is quite useful in distinguishing other chromosomes as well.

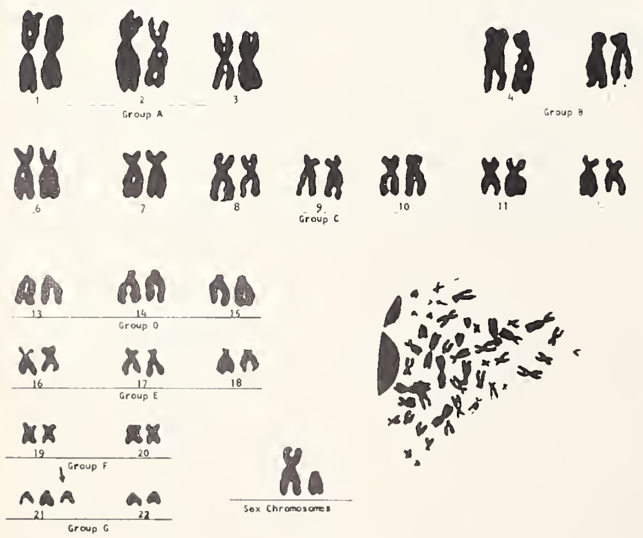

Figure 3

Extra acrocentric chromosome in G group. G trisomy Down's Syndrome (peripheral blood).

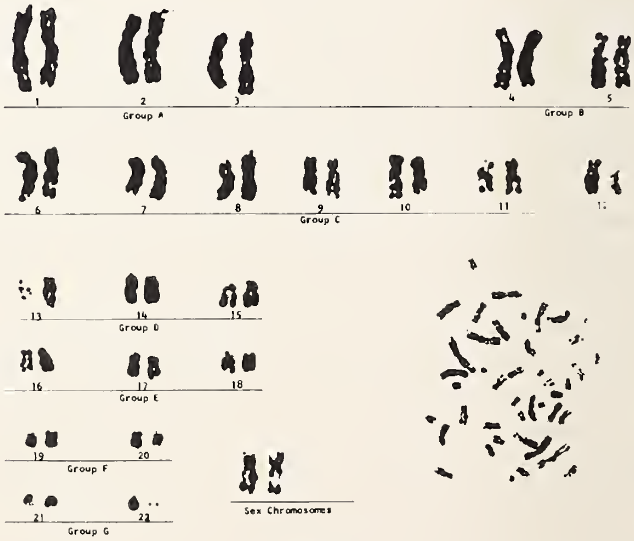

Figure 4

Giemsa-Trypsin Banding Technique. Note the banded staining of chromosomes (peripheral blood).

Recently the Q-Band,[14] G-Band,[15] and C-Band[16] and R-Band[17] techniques have gained wide acceptance. Certain portions of the chromosomes are digested by the trypsin and the chromosomes show rather definite and constant bands. This banding technique further helps to identify various chromosomes (Fig. IV).

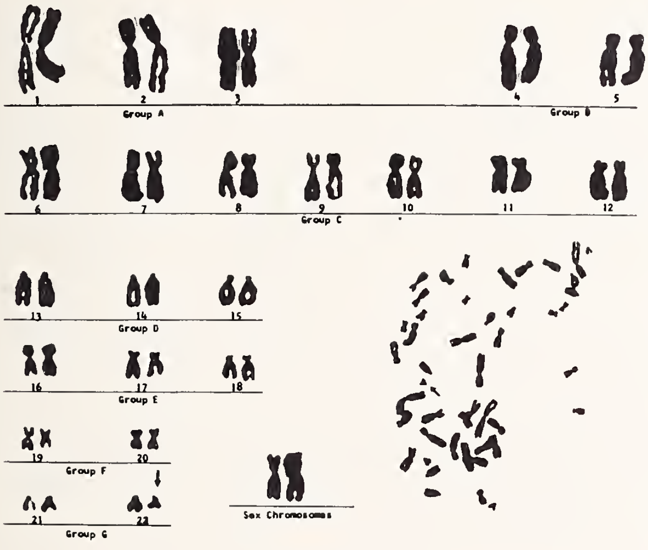

Figure 5

A case of chronic myeloid leukemia showing Philadelphia chromosome (Ph^1). Note the size of the chromatids, smaller than other G chromosomes (bone marrow).

A bone marrow sample[18] is best used in most hematological cases, particularly the Ph^1 [19] chromosome identification (Fig. V). A suspension of tumor cells is used for chromosome analysis for marker chromosomes in cancers. However, peripheral blood lymphocyte culture is most practical for chromosome analysis in clinical medicine.

Basic Forms of Chromosome Aberrations

Basic forms of chromosomal aberrations are numerical and structural aberrations. Most common forms of numerical aberrations are trisomies (47 chromosomes with one extra chromosome e.g. Klinefelter's and Down's syndrome) and monosomy (45 chromosomes with one less chromosome, usually involving X chromosomes e.g. Turner's syndrome). Structural aberrations are less commonly seen in clinical medicine and these include translocation, deletion, inversion, duplication and shift of chromosomes or chromatids. Formation of isochromosomes and ring chromosomes also belong to the structural aberrations. During the past 10 to 15 years, a vast amount of information has been documented concerning chromosome abnormalities, including some information on genetic mapping. It is not the intent to review all of these findings, but merely to touch upon the more well established conditions or syndromes related to some form of chromosome abnormality.

A. Down's Syndrome

I. G. Trisomy-Down's Syndrome

These cases are classified as G trisomy since there is one extra chromosome in the G group. Many investigators carried out chromosome studies on phenotypically characteristic Down's syndrome and found that most of them showed G trisomy and that the condition is not hereditary. It was found that G trisomy is maternal age related and caused by nondisjunction during meiosis.[20] In other words, one of the daughter cells receives 24 chromosomes and the other 22 chromosomes in lieu of 23 chromosomes each. When the cell with 24 chromosomes (one extra G group chromosome) is fertilized with a normal sperm, then, there will be 47 chromosomes. The other cell with 22 chromosomes apparently is not compatible with life.

II. D/G Translocation, Hereditary Form of Down's Syndrome

Robertsonian fusion of mammalian chromosomes has been noted in humans, and when it occurs, the term translocation is used. The chromosome count of a given cell shows 45 chromosomes or more in these individuals, but the karyotype of the chromosomes shows one of the chromosomes fused to another at the centromere.

A very important translocation in the human is D/G translocation and G/G translocation. A young mother who is a carrier of D/G translocation has 45 chromosomes and one of the G group chromosomes is missing. However, one of the D group chromosomes shows an extra chromosome fused at the centromere. In essence, this extra small chromosome is the missing G group chromosome. Therefore, this mother is normal in every respect, even though she has only 45 chromosomes. If she is conceived by a normal sperm, carrying 22 autosomes and one sex chromosome, either X or Y, (which will determine the sex of the offspring) there is a 25% chance of the conceptus having one of the mother's D group chromosomes carrying translocated G chromosome, plus normal number of G group chromosomes. There will thus be an extra G chromosome, which is essentially a trisomic situation, with a chromosome count of 46, not 47. (Fig. VI) This individual will show all the phenotypical features of Down's syndrome.

A translocation carrier mother will have 25% chance of normal pregnancy, 25% miscarriage and 25% chance of having D/G carrier, like mother, and 25% D/G translocation type Down's syndrome.

Contrary to Trisomic type of Down's syndrome which is maternal age dependent, (older the mother, higher incidence), translocation type of Down's cases

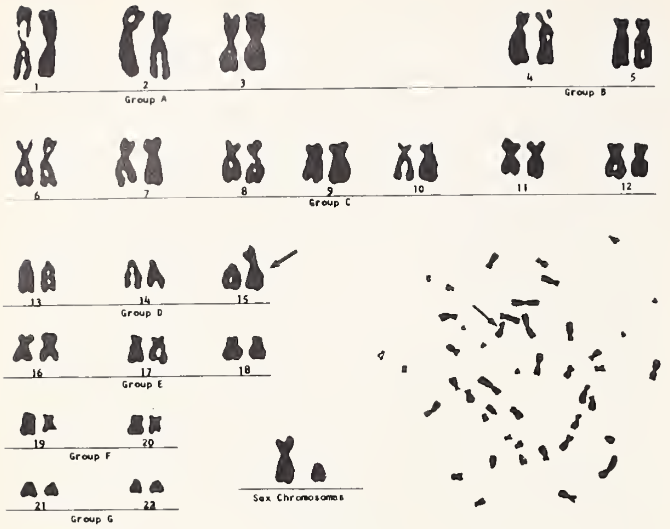

Figure 6

D/G translocation type Down's syndrome. Note the extra chromosome fused at the centromere of one of the D group chromosomes.

usually are more often seen among the younger mothers. Fortunately this type of Down's syndrome is less than 10% of all Down's cases.

III. G/G Translocation, Down's Syndrome

Another even more rare form of translocation is G/G translocation. In this case two chromosomes of the 21-22 group (G group) have fused at the centromere. In general, the 21-22 centric translocation seems to be mainly transmissible through the father and a significant increase in the paternal age has been noted in this type of chromosome abnormality, the mean age of the fathers was 42.5 years. If the translocation chromosome were an isochromosome of the long arm of No. 21 or a fusion between the two 21 chromosomes, all of the offsprings of carriers would be expected to be Down's anomaly because every viable gamete would contain the isochromosome or fusion.

Every Down's case should be studied by cytogenetic technique so that physicians can offer a better genetic counseling for the family involved.

IV. Mosaicism and Down's Syndrome

Mosaicism can be seen in many chromosome abnormalities including sex chromosomes but Down's syndrome also shows mosaicism. Mosaicism consists of more than one cell line showing mixture of either normal, abnormal or abnormal and another abnormal chromosome compliment in an individual. For example, XX/XO Turner's syndrome 47 G Trisomy with normal cell line of either XX or XY, XY/XXY Mosaic Klinefelter's syndrome and sometimes XXY/XXYY, XYY/XYYY, XO/XX/XXX etc. are seen. Numerous combination has been seen. Frequently phenotypical borderline cases of Down's show such a mixed cell line, sometimes with much higher I.Q. (and some of these cases can be quite self sufficient). It must be pointed out that in mosaicism, abnormal cell line may be present in skin fibroblasts culture yet peripheral blood lymphocytes may show normal findings and vice versa. In other words, chromosome analysis of blood alone may miss mosaic Down's cases, and other mosaicism.

B. D Trisomy, E Trisomy

Other chromosome groups can also have non-disjunction during meiosis, and when this occurs in the D group, D Trisomy; in the E group, E Trisomy. These cases are compatible with life during the embryonal stage, even though they have multiple congenital abnormalities. A and B Trisomy apparently are not compatible with life during the embryonal stage. C Trisomy, however, has been observed in some hematological disorders. All of these trisomy cases have 47 chromosomes.

C. Klinefelter's Syndrome (XXY Syndrome) and XYY Syndrome

When there is an extra X chromosome in a phenotypical male, the sex chromosome consists of XXY instead of XY (Fig. VII). This syndrome has been known since 1942,[21] but it has been recently found[22] that these patients have one extra X chromosome. More recently XYY[23] bearing males have been reported and there is some evidence that these individuals are more often found among the groups with antisocial or criminal personalities. (Fig. VIII)

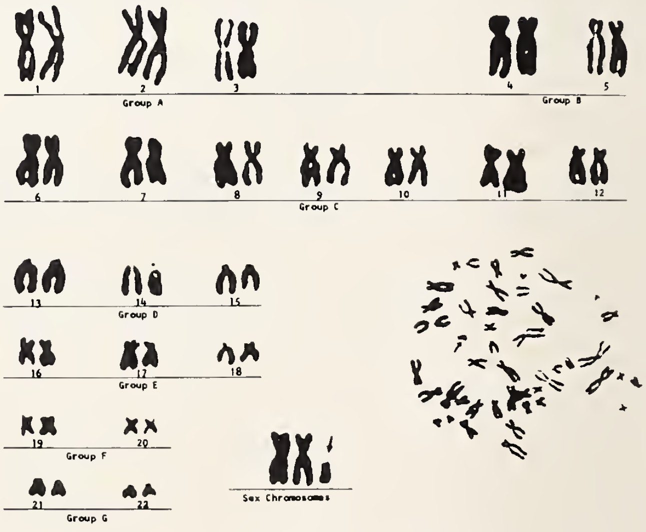

Figure 7

Klinefelter's syndrome showing XXY sex chromosomes.

D. Turner's Syndrome, XO Monosomy

There are individuals with 45 chromosomes, one less than the normal number. Turner's syndrome is caused by such a chromosome abnormality. These

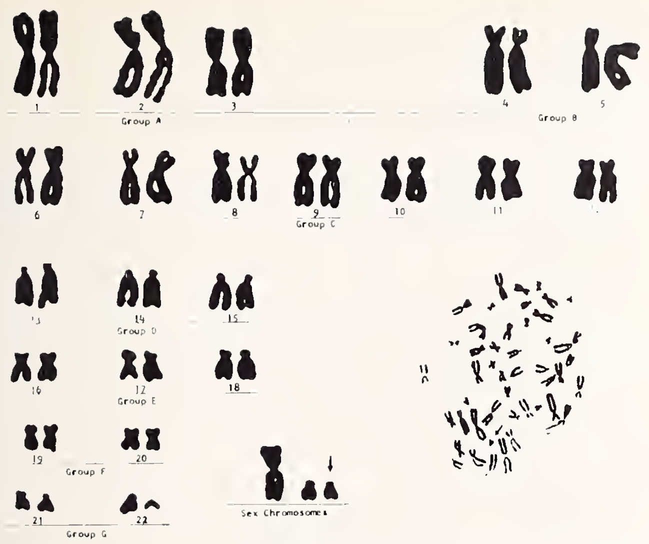

Figure 8
XYY syndrome showing one extra Y chromosome.

individuals have one less sex chromosome, only one X chromosome. This is termed XO monosomy. (Fig. IX) During meiosis one X chromosome is lost due to non-disjunction. Obviously, non-disjunction caused one cell to have one extra chromosome, producing a trisomic cell, whereas, the other cell is left one less chromosome, producing monosomy. Monosomy involving autosomes has not been observed in humans clinically. These patients will show no Barr bodies in their buccal or vaginal smears, for Barr bodies are second X chromosome seen with the nuclei. Incidentally, so-called superfemale with XXX or XXXX sex chromosome constitution have been seen and these cases will have 2 and 3 Barr bodies in their buccal smears respectively. Mosaic Turner's XO/XX is also known.

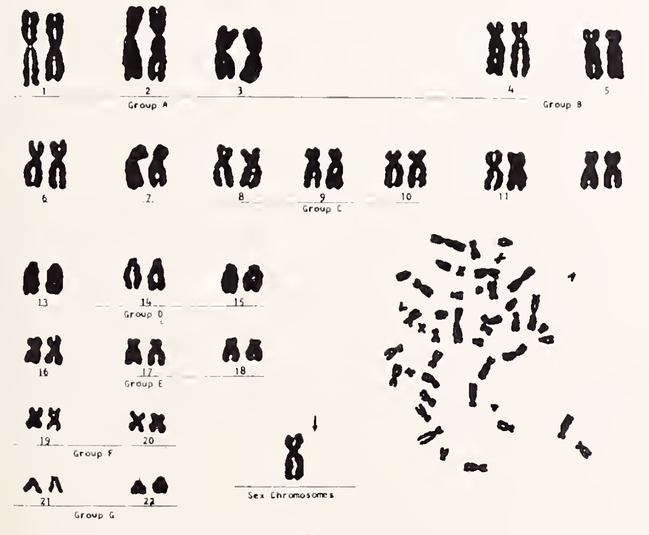

Figure 9
Turner's syndrome showing 45 chromosomes, XO monosomy.

E. Chronic Granulocytic Leukemia and Philadelphia Chromosome, Ph^1

The Ph^1 chromosome appears in approximately 60% to 80% of chronic granulocytic leukemia. This chromosome is one of the small acrocentric chromosomes, G group chromosome lacking about half of its long arm, an example of pseudodiploidy (normal number of 46 chromosome but one or more of them exhibits structural aberration).

It has been noted that Ph^1 negative patients have a poorer prognosis than Ph^1 positive patients. Ph^1 negative patients tend to have early thrombocytopenia and also responds poorly to therapy with a median duration of survival from the time of diagnosis of only 18 months compared with 45 months for Ph^1 positive patients.

Ph^1 chromosomes are found in *bone marrow cells* during remission as well as during relapse. The Ph^1 chromosome does not disappear with clinical or hematological remission. However, this chromosome may be absent in peripheral blood during remission.

F. Acute Granulocytic Leukemia and Chromosome Abnormality

In actue granulocytic leukemia, various chromosome abnormalities are found, such as hyperdiploidy (more than normal number of chromosomes, at times over 100 in a single cell), hypodiploidy (less than normal number of chromosomes) and pseudodiploidy (normal number of chromosomes with aberration or structural changes of chromosomes). Sequential chromosome studies of these patients show that a favorable response is marked by an early disappearance of the chromosome abnormality with an increase of normal diploid cell lines. Also it has been observed that abnormal chromosomes will reappear in relapse.

The median survival after initiation of anti-leukemia therapy of patients with acute granulocytic leukemia with chromosome abnormality was shortened (7.2 months) than those without abnormal chromosomes in the bone marrow. (9.1 months).

G. Cri du Chat Syndrome[24] [25]

There are some syndromes due to deletion of a portion or portions of a chromosome and one good example is Cri du Chat syndrome caused by the deletion of the short arm of the B group chromosomes. Apparently, the infant has a malformed larynx and the infant's crying is very similar to the cat's meowing.

Indications

In clinical medicine, chromosome analysis is recommended in the following situations:

A. All congenital malformations, including cardiac anomaly, polydactyly, syndactyly and suspected and known Down's syndrome. (All forms of Trisomies)

B. Phenotypically suspicious Klinefelter's and Turner's syndromes.

C. Primary amenorrhea and infertility. (XO and XXY and their mosaic forms)

D. Acute and chronic granulocytic leukemia and myeloproliferative disease. (Ph^1 chromosome and hyper, hypodiploidy)

E. Prenatal determination of chromosome compliment. Recommended for mothers who had children with a known chromosome abnormality. Amniocentesis is required during first trimester.

F. Ambiguous genitalia. (Gonadal dysgenesis, pseudo and true hermaphroditism).

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The Psychological Problems of Ostomates

Austin McCawley, M.D., Henry Mannix, Jr., M.D., and Dorothy D. McCarthy, R.N.

Patients who have had an ileostomy, urostomy or colostomy experience a profound threat to their sense of physical integrity and their self-concept. Some degree of emotional difficulty is usual under the circumstances and recognition of these emotional factors is important in the care of the ostomy patient. The psychological problems are most intense in the first year after operation but they may continue, either as a generalized discontent and lack of peace of mind or in the form of more complex psychological symptoms. That these difficulties can be surmounted, however, is demonstrated by the many patients who have coped successfully with the necessary readjustments and lead productive, satisfying lives.

In making the difficult decision for surgery, the prime consideration is the physical health (or survival) of the patient but the psychological reactions to the operation should be considered in the treatment plan.

Common anxieties felt by patients after operation include fear of spillage from the stoma, fear of embarrassment in certain situations requiring exposure of the bag, worry about detectable odor and concern about sexual adequacy and attractiveness. The latter may be particularly difficult for a patient to express; women patients seldom bring up their sexual concerns to nurses. Sometimes a physician or nurse may unconsciously turn off a patient from discussing these more sensitive problems because of their own reluctance to look at the issues. However, a sensitive interview will reveal the sexual and other concerns which are experienced in some degree by every ostomate.

Underneath lies a deeper sense of grief for the actual or presumed loss: loss of anal control, loss of the resected bowel, loss of attractiveness, sexual appeal, femininity or potency. The control of urination and defecation is one of the earliest achievements of the individual and these functions are bound by strong emotional associations. To the adult incontinence is intolerable and implies a return to infancy and helplessness, with concomitant loss of self-esteem. The personality type, previous experience and the psychological set of the patient before operation, influence the subsequent emotional reactions. The more compulsive and perfectionistic personalities are particularly vulnerable and may become obsessed with the difficulties of the post-operative adjustment. Patients who have had previous psychiatric disturbances, unconnected with the illness that necessitated surgery, may have exacerbations or recurrences of these disorders and the problems connected with ostomy are added to the pre-existing psychiatric difficulty.

Some cancer patients have a special difficulty in accepting the stoma. These persons had few symptoms before the diagnosis of cancer or else have suffered for only a short period of time and the benefit derived from the operation is for them a highly theoretical value, unsupported by much in the way of real, personal experience. They express the feeling, "what happened and why did it happen to me?" and find it hard to accept the reality of the operation and the resulting stoma. The nursing staff may find them harder to teach in post-operative training.

Patients with ulcerative colitis have generally had years of suffering before they get to the point of ileostomy. The psychological problems of ostomy are compensated for by a considerable improvement in physical health; they are no longer in pain, they can stop worrying whether they will make it to the bathroom in time, they put on weight and they generally feel a lot better. They do have problems similar to those of cancer patients with the additional complication that ileostomies are more difficult to manage. It is recognized that ulcerative colitis is associated with personality factors and these characterological problems persist after operation. However, they are less obtrusive and may only be revealed in times of increased stress.

At one time psychiatrists were concerned that the improvement in symptoms after ileostomy would be temporary and symptom alternation would occur, i.e., a basic psychologic disturbance would come out in other psychosomatic symptoms or overt psychiatric disorder, perhaps even psychosis. These predictions have not been fulfilled and symptom alternation does not seem to take place.[1]

This fact does not invalidate theories about psychogenic etiology. The success of behavioral therapies in certain psychiatric syndromes has made us revise our ideas about symptom alternation. Many clinicians are still impressed with the importance of psychological factors in ulcerative colitis, although current thinking seems to favor the concept of it as an auto-immune disease with a genetic basis. Other

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possible causes are infection, allergy, nutritional deficiency and enzyme defect; the etiology remains a mystery.

An interesting observation made by nurses who work closely with ostomates is that the ileostomy patients usually dominate meetings of the Ostomy Association. We have not looked into this particular matter but informal comments by several observers give an impression that they are, by and large, more compulsive and aggressive personalities.

The emotional reactions that have been described all tend toward the development of a depression. Most patients after ostomy struggle with some degree of depression, either minor and realistic in proportion to the difficulties and losses experienced or disproportionate, severe and incapacitating.

Depression is a reaction of deep and unusual sadness and melancholy that occurs in response to the real or imagined loss of a valued person, object or state. It may also occur as part of manic-depressive illness, an illness in which precipitating, reactive factors are secondary. A patient with manic-depressive illness may experience a recurrence after ostomy, either a manic or a depressive episode, but this is a special problem beyond the scope of this article.

The depressed patient experiences a sense of hopelessness that ranges from moderate pessimism to deep despair. He has a pervasive sense of guilt and unworthiness and the loss of self-esteem is a feature that distinguishes pathological depression from normal grief. The patient may believe that he is a failure, has let his associates down or has hurt his family. In severe depressions the anger toward the self may result in suicidal thinking and perhaps in an actual attempt at suicide.

Depression is accompanied by characteristic physical symptoms. Among the earliest of these is fatigue, which is further aggravated by insomnia. Early morning awakening is a frequent complaint. Typically, the patient feels worse in the morning. Previous interests are lost; motor activity and thinking may be retarded. Some degree of anxiety is usually present and may range from mild apprehension to severe anxiety with physical agitation. Loss of appetite and weight, constipation, elevation of blood pressure and other physiological disturbances reflect an autonomic imbalance. Loss of sexual libido is common.

Often the patient complains only of the physical symptoms of depression, not recognizing or suppressing the emotional disturbance. He may become quite hypochondriacal, complaining of an endless variety of physical symptoms which serve to obscure the depression. Ostomates may focus on the physical inconveniences of the stoma, mechanical difficulties in using the appliance and other minor physical discomforts. Sometimes overweight becomes a problem for the ileostomates; this may be an overreaction to improvement in their alimentary regulation but it can also be a defense against depression.

Underneath the depression lies a buried anger that may come to the surface and reveal itself either directly or indirectly. It is our impression that male ostomates are more able to express their anger directly; women suppress it and either become more depressed or else bring it out indirectly in resistant behavior patterns, i.e., refusal to eat, refusal to learn the necessary techniques for using the appliance. Men may show similar reactions, however.

Whatever the pattern of response, patients need to express their feelings of grief and anger and their fears, including the fear of death. This can best be done in context of a relationship with the treating physician and the nursing staff. Under the pressures of surgery, strong emotional bonds are created between patients and those responsible for their care. The quality of these relationships is of great importance to the patient and provides the basis and the opportunity for strongly supportive psychotherapy.

The groundwork is laid down in the earliest stage of pre-operative care and the role of the nurse in psychological preparation of the patient for surgery is all-important. The physician will provide basic explanations but the patient needs more time to ask questions and to ventilate his anxieties. The ideal situation is for the nurse to visit with the patient and family several times prior to surgery. She should determine what and how much to tell about the operation by the questions asked by the patient and the response to answers given. To bombard a person with information he or she is not ready or willing to handle does little good and may do some harm. The patient will indirectly let you know his or her individual needs and wishes.

It is most important that everyone involved in the patient's care support him or her in taking a positive attitude toward the operation and the resultant stoma and be very careful not to communicate any negative attitudes toward the stoma. Patients may pay more heed to a casual aside from a nurse than to considered advice from a physician. They know that they are being reassured and may discount the "official line," regarding an offhand comment, made thoughtlessly on the spur of the moment, as more indicative of what people are really thinking.

In many cancer operations it is impossible to predict the likelihood of a permanent ostomy. A more pressing question is whether the tumor can be removed at all and although the surgeon must obtain informed consent, he does not want to go into more detail and arouse more anxiety before operation than is absolutely necessary. Once again the questions asked by the patient and his response to the answers give the cue to how much information he should have. Physician and nurse have to play this one "by ear."

When a firm relationship and good personal interaction has been established between patient and staff the post-operative recovery is likely to be much smoother. Continuity of care throughout the hospital stay is a must. Detailed records of patient teaching should be kept and referred to both pre-operatively and post-operatively. A patient's readiness to learn and accept is very individual. As already mentioned, a patient who receives quick relief of symptoms usually advances at a more rapid rate than one who has not been beset by symptoms prior to surgery. In this era of stress on bed utilization and the push to move patients out of the hospital as quickly as possible, the mistake of treating all ostomies the same must be avoided.

Appliances and accessories, both essential and non-essential, are also very individual. A pale blue ileostomy bag or a lace covering for the bag, although not considered "standard equipment" can meet a great need for some patients. Nurses should be aware of what is on the market and not be stereotyped in their guidance of patients choosing equipment. The acquisition of an efficient, acceptable appliance and the ability to use it is very important to an ostomate's sense of assurance and self-esteem.

No single factor is as important to the emotional adjustment of the ostomate as the attitude of their loved ones and the support and education given to the patient should also be extended to the family. This will be accomplished more successfully if a relationship has been established with the family before operation.

The United Ostomy Association is an organization of patients with ostomies who have joined together for mutual help. This very effective group which has branches throughout the country, has been of great assistance to many people and can be called on in the training period after operation. Nothing makes a task so easy as sharing it with someone who has been there himself.

With psychological support, teaching and the opportunity to express and work through feelings, the patient gradually loses his sense of helplessness, accepts his loss and can turn his energies to the future. Problems may persist, however, taking the form of confusion and anxiety about sexual roles, alteration of the self-image, shame and embarrassment in situations where the stoma might be exposed, and diminished self-esteem. Some patients describe a generalized discontent and lack of peace of mind, in spite of a sense of physical well-being. For many, however, the anxieties are concerned predominantly with sex.

Most of the sexual problems of ostomates are psychological but in a certain number of cases they are organic in nature. This is nearly always in males and results from damage to the autonomic nerve supply of the genitals in rectal surgery, usually cancer surgery, where excision cannot be confined to the immediate area of the rectum. Rectal surgery does not interfere with the sexual function of the female to the same extent unless there is extensive surgery, e.g., pelvic exenteration which includes removal of the vagina. After abdominoperineal resection some women may experience reduced sensation and some reduction in satisfaction from intercourse but this is usually not a major problem.

Erection results from parasympathetic stimulation through the parasympathetic sacral outflow, represented by the nervi erigentes or pelvic nerves; ejaculation results from sympathetic stimulation through the thoracico-lumbar outflow which forms the hypogastric plexus; orgasm involves both sympathetic and somatic nerve stimulation, the latter through the pudendal nerve. Damage to these nerves will produce impotence, orgasmic dysfunction and ejaculatory incompetence. Retrograde ejaculation may occur during orgasm, i.e., the seminal fluid is propelled backwards into the bladder.

As a rule, orgasm and ejaculation are first to disappear after nerve damage, followed by erection;[2] However, after abdominoperineal proctosigmoidectomy erection is most jeopardized. Recovery of potency may occur even many months after surgery, possibly because psychological factors are responsible, possibly because a second set of pelvic nerves, i.e., their lateral branches, as described by McCrea and Kimmel,[3] substitute for the loss of the main set.

Comarr[2] studied 19 patients following abdominoperineal extirpation of the rectum. Thirteen lost all sexual function; two patients had erection and orgasm without ejaculation—one of them ejected occasionally urine; two additional patients had orgasm without erection or ejaculation. Goligher,[4] on the contrary, found that among 95 patients, 72% retained erections, 64% could have intercourse and 61% had undisturbed ejaculation. All of the patients in this study had rectal surgery for cancer.

In general it can be said that the effects on sexual function are much less when the rectal surgery is for ulcerative colitis. The sexual difficulties in the various ostomies are summarized as follows:

Ileostomates

Most of the sexual problems occurring after ileostomy are psychological in origin and temporary in duration. Because of the improvement in general health some ileostomates report improvement in sexual performance. Stahlgren[5] et al reported on the influence of abdominoperineal resection for ulcerative colitis on sexual function in 25 men and 26 women. Of the men, 18 reported that sexual performance was the same, 5 said it was worse and 2 found that it was better. Of the women, 23 showed no impairment, 2 found it worse and one better. Donovan and O'Hara[6] interviewed 21 patients who had rectal surgery for ulcerative colitis. Ten noted no change and 9 noted improvement in sexual function. Only 2 reported sexual difficulties and one of these had extensive excision of the lymphatics because the lesion had been mistakenly diagnosed as malignant. The other had transient difficulties with erection for one year but thereafter improved and sired a child.

Colostomates

The results after surgery depend on the degree of damage to neural structures and the combination of symptoms is variegated. Some patients are fully potent; some cannot have erection but achieve orgasm; many who have orgasms cannot ejaculate; some cannot have erections but can have orgasms; and some can have neither erections or orgasms.

Within six months the patient usually will know how much sexual function has returned. Time is the important factor and it is unwise to make predictions.

Urostomates

If the bladder has been removed the patient will be impotent. Otherwise, the type and degree of sexual disturbance depend on the condition for which urostomy was indicated. In neurologic disease the patient may already have a sexual deficit before the urostomy is performed. In malignancy the loss of function after the operation will depend on the extent of surgery required. Sterility and ejaculatory incompetence are common sequelae; age is a factor and impotence seems to be a common result in patients who have their urostomies later in life.

Psychological Factors

In most ileostomies and in many cancer patients, the problems are psychological. In males the principal symptom is impotence, which is usually due to one or more of the following factors:

1. Serious anxiety about sexual performance, the attractiveness of an altered body, the possibility of odor and the efficiency of the appliance or other stoma covering.
2. Failure because intercourse is attempted too soon after operation, before the patient is physically strong enough.
3. Depression.
4. Excessive sedation or alcohol.

The latter three are more important in the postoperative phase; the first is a basic problem that is encountered and re-encountered over a period of time.

Impotence is usually temporary, ceasing to be a problem as the initial anxieties about resumption of sexual life are overcome. The assistance of an understanding partner is most important. Counseling by the physician will help to prevent unrealistic anxieties and to reassure the patient that he can resume an active sex life. When there is organic impairment of sexual function, adjustments have to be made and the limitations allowed for, but the fact of organic deficit need not mean an end to sexual life. When the partner is understanding and the couple willing to experiment, sexual compromises that are physically and emotionally gratifying can sometimes be worked out. It is important that the physician be sympathetic, enlightened and open-minded.

Women ostomates in the younger age groups are usually concerned about whether they will be able to bear children. At one time many physicians told women that they should not become pregnant after ostomy. That would be regarded as nonsense today; pregnancies after ostomy are usually free from trouble.

In evaluating sexual problems of the ostomate it must be remembered that they are influenced by problems that may have existed before surgery. Not uncommonly, an ostomy is blamed for sexual difficulties that have other causes.

The United Ostomy Association has published a number of excellent pamphlets on the subject of sex and the ostomate. Their titles are: Sex, Pregnancy and the Female Ostomate;[7] Sex and the Male Ostomate;[8] and Sex, Courtship and the Single Ostomate.[9] It should be standard practice to recommend that every patient read them. The physician will also find them very helpful; they go into considerable detail and give useful, practical suggestions about the management of the more common problems. They also provide a talking point, around which the patient can open up and talk about his feelings and anxieties.

The ways in which individuals handle the adjustment to ostomy reflect their personality, their previous experience and their ability to cope with stress. When more serious difficulties arise, e.g., a clinical depression, the psychiatrist should be called in consultation. However, psychological help should be the concern and responsibility of everyone on the surgical, medical, and nursing team and should be an integral part of the treatment plan from the very beginning. The most effective role for the psychiatrist may be that of consultant to the treating physicians and nurses. Whenever possible, the psychological approach should start before operation. Patients in this crisis period not only need more psychological help, they are more receptive to it and the effects will show later on.

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Reflections From The Dean's Office

Robert U. Massey, M.D.

The new National Health Planning Act (PL 93-641), not surprisingly, puts support of primary care programs at the top of its list of national health priorities. Education for primary care has been high on the priority lists of medical educators for a decade now. For most of us the term "primary physician" seemed first to appear in 1966 in the Report of the Citizens Commission on Graduate Medical Education, the Millis Report.

Words and combinations of words often accumulate a burden of meaning far heavier than that intended by their inventors. At first that accretion of new meanings distorts and later completely hides the original sense. The identification of certain words, phrases, and literary styles with political or social movements has given them power to evoke undeniable emotional responses which render them useless for little more than polemics or demagoguery.

At other times a new word or phase, or an old one used in a new way, becomes a code for some idea or concept which had been seeking to adopt a suitable expression. When this new meaning becomes dominant, but is local in time and place, it becomes for us a "dangerous sense" of the word, as C.S. Lewis described it. He said it was the meaning which lies uppermost in our minds. "Wherever we meet the word, our natural impulse will be to give it that sense. When this operation results in nonsense, of course, we see our mistake and try over again. But if it makes tolerable sense our tendency is to go merrily on. We are often deceived."[1]

For some of us, "primary care" is to read "family medicine." If that signifies the new specialty which is designed to provide comprehensive, continuing care of the patient within the context of his family, we may be deceived by one of the dangerous senses. If the meaning is temporarily restricted further by reading "general practitioner" for "family physician," a dangerous sense has now taken over which may render any further discussion meaningless. As the lawmakers use it, it seems to have something to do with care of the disadvantaged—another dangerous sense.

When I first read the Millis Report, I substituted "internist" for "primary physician." That squared with my necessarily limited experience. Many internists believe that 70-80 percent of their time is spent providing primary care, according to their sense of the meaning of that term. Pediatricians also think that, and so may gynecologists.

For others caught up with the concept of physician assistants, primary care can be read as "physician extender programs." Nurses see nurse associates rendering primary care.

Multispecialty group practices believe they have always provided for the entire spectrum of care, including primary, and cannot see what the fuss is all about.

Ask any committee or academic department to define primary care and you are in for a day of it. If the concept is that unclear, it will be difficult to agree on any definition which does not square with our individual perceptions of reality, and so we shall go on using the term with all its dangerous meanings.

That will make planning and designing a system or an educational program very difficult. Perhaps in the long run that sort of protection from the planners is in our best interests; it provides time for the forces of the market place to work their will. If primary care, whatever that turns out to be, is paid for as handsomely as the more technically complex kinds of care, the profession and the health institutions will respond.

It will be unfortunate if anyone who can influence legislation should try to get laws passed which would permit only one kind of response. A major effort in preventive medicine and patient education could make the primary care problem inconsequential; it could turn out to be little more than what the patient knows enough to do for himself, or for his child or neighbor. If our failure to define the term or our lack of clarity about the need should lead us away from a primary emphasis on prevention and patient education, we shall have lost valuable years and billions of dollars.

ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut, School of Medicine, Farmington.

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The President's Page

The superintendence and management of the Connecticut State Medical Society is vested in its House of Delegates. This House of Delegates is the legislative body of the Connecticut State Medical Society and meets twice a year. It is composed of the officers of the Society, the members of the Council and delegates from each of the eight Counties of the State in the apportionment of one delegate for every thirty-five members of the County Societies or fraction thereof.

In between meetings of the House of Delegates the business of the Society is carried on by the Council, by the committees of the Council and by the committees of the House. The committees report to the Council and if they are committees of the House, to the House as well. The Council meets regularly once a month and is made up of thirty-two members, three from each of the three large counties, two from each of the five small counties, the seven officers, the three delegates to the AMA and the three alternate delegates to the AMA.

Regular meetings of the Council start at 2 p.m. and usually go on for five or six hours, and even at that they don't always get through the agenda. A lot of brainstorming goes on at these meetings, some of which, it is considered by some, as a waste of time. But in actuality it isn't a waste of time, for each member of the Council must be given his say if any semblance of democracy is to be insured.

With these things in mind, it becomes evident that each member of the Council as well as those members who make up the committees spend a great deal of time each year without pay working for the physicians of Connecticut and their patients.

It is frustrating for the leadership to hear occasionally that they are a small clique of politicians working in smoke-filled rooms conniving ways to make things inconvenient for physicians at large or asking questions such as: "why don't you guys do this? or why don't you guys do that?" That we are a small clique is not true. What is true is that we are you. There are ways to communicate with the leadership.

The most direct way to communicate is to write to the President or the Chairman of the Council or any other officer or councillor and state what is on your mind. He will bring the problem to the Council.

The most solid way to do it is to bring the matter up through your County Society to the Council. This can be done either through a County meeting or through the governing body of the County.

Another form of exchange is *Connecticut Medicine*, as the official Journal of the Connecticut State Medical Society, which acts as a medium for exchange of ideas. Dr. J. Alfred Fabro, the Editor, has done an excellent job in content and format in the last two years.

Only five to 10 percent of practicing physicians in the country participate in the affairs of organized medicine. The leadership needs new blood and new ideas. Too many keep their ideas to themselves and criticize from time to time without being willing to participate. This criticism erodes and destroys accepted structures without building anything new to take their place.

The plea is to get more physicians to participate at all levels: County, State and AMA. First join and then become active. In this way we can come to a cohesive opinion and then fight for it.

James H. Root, Jr., M.D.
President

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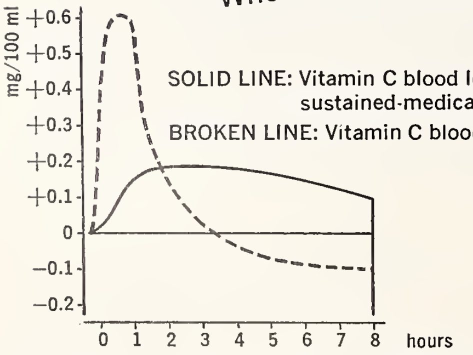

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Commencement Address

Dr. Robert W. Berliner, *Dean of the Yale University School of Medicine*

I would like first to congratulate each of our new graduates, in public health and in medicine, on the completion of this, the formal stage of their education, and welcome them to the challenging and uncertain, but vastly rewarding domain of the so-called health care system.

This is a time of rapid change in the world of medicine and health care. Not only is the substance of medicine growing at an ever accelerating rate, but the forms in which medicine relates to society are also undergoing rapid metamorphosis. To the extent that your education here has been successful you will be able to adapt readily to these changes, perhaps to help shape and contribute to them, but, in any case, to sort out the new ideas and new methods, to discard what is false and useless, to doubt and question what is dubious, and to assimilate and apply what is true and useful.

It is difficult, indeed, to try to predict the form of the health care delivery system within which you will operate, but my cloudy crystal ball reveals something like this: with both the conservative administration and the more liberal elements of Congress pressing for some form of national health insurance, the adoption of some such measure seems only a matter of time, and not too long a time at that. The advent of universal coverage is certain to have far-reaching effects on the system within which health care is dispensed. Unless special provisions are made to subsidize those who participate in prepaid group systems, these are likely to disappear totally from the scene. The great attraction of such plans for their subscribers lies in their ability to spread the risk—essentially to provide insurance. The participant exchanges some of the freedom of his choice of medical care for the assurance that his costs for care will be limited to the enrollment fee. However, if he is relieved of the concern for his costs and can be assured that his costs are covered, he will remain uncommitted and choose his source of health care only when the occasion arises.

The disappearance of the prepaid group systems would be particularly unfortunate since it is reasonably predictable that within not too long a period it would be necessary to re-establish them as a method of controlling the costs of the insurance system. The health care bill already exceeds $90 billion and universal insurance applied to a fee for service system is, I believe, bound to increase the bill for services substantially and progressively. My guess, then, would be that most of you will, as physicians, operate within the groups providing health care under the contract to defined populations, or as administrators, helping to organize and administer such systems.

Organization along these lines will, I believe, tend to foster specialization, a direction that it is currently popular to deplore. I will admit to not sharing the view that specialization is deplorable. I do not believe that it reflects a flight from concern for patients as individuals, nor do I believe that it is particularly a response to the higher income of the specialist. I believe it is driven largely by the enormous growth of medical knowledge and capability that makes it nearly impossible for the physician to maintain a high level of competence in anything but a limited sphere. Many people retain the nostalgic illusion that somehow things were better in the good old days when the general practitioner, preferably arriving by horse and buggy, seemed available to make a house call at any time of day or night. What is not generally remembered, however, is that admirable as he may have been, and whatever comfort and reassurance he may have offered, the chances that he might be able to alter significantly the course of his patient's illness, at least in a favorable direction, were minimal.

The great improvement in our ability to deal with the problems of our patients is a direct consequence of the progress in medical science and its application. And, as is the case with the development of new technologies in other spheres, the answer to the problem is not to discard the technology, but to devise new methods for dealing with the undesirable secondary effects. Perhaps the physician's associate has some role to play in the solution.

However, great as have been the advances in medicine, it is clear that we have no reason for self-congratulation and complacency. No one who is exposed to clinical medicine can fail to recognize that the unsolved and half-solved problems vastly exceed those with which we can deal effectively. Much of what we can do is in the area of what my perspicacious and articulate predecessor, Lewis Thomas, has given the name of "half-way technology." The prototype is the iron-lung for the management of the polio victim—the expensive and elaborate

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The Dean's speech was delivered to the 1974 Yale medical and public health graduates at the School of Medicine's commencement ceremony in the Mary S. Harkness Auditorium in May.

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device to compensate, in part, for the damage already done; the simple, inexpensive solution is a polio vaccine. We have many current analogues—coronary by-pass surgery and the coronary intensive care unit rather than the prevention of coronary atherosclerosis; radical surgery, chemotherapy, and radiation for cancer, rather than an attack on the causes.

It is obvious to any one that preventive medicine is far more desirable than therapeutic medicine. Unfortunately, we know how to prevent precious few diseases. Preventive measures, however, do not come simply from good will and determination, but from better understanding of normal and abnormal biochemistry and physiology and of the pathogenesis of the disorders we would prevent. We know how to prevent a number of diseases, mostly infectious, because we have learned how they are caused, how they are spread in the population, and we have devised methods to interfere. With most diseases we do not have this knowledge and it can come only from the efforts of medical science—from intensive study of individual patients and from the laboratory.

Our ultimate goals are still far ahead of us and you need have little fear that medical research will put you out of business. In fact, the conquest of one problem only increases the importance of those that remain. And we can expect this to continue until we have achieved for man that happy end described by an earlier physician, Oliver Wendell Holmes, in his poem "The Wonderful One-Horse Shay," about a carriage that ran perfectly for 100 years and a day, and then collapsed in a pile of dust. Let our motto, then, be "every man a one-horse shay."

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Letters To The Editor

Letters to the Editor are welcomed and will be published, if found suitable, as space permits. Like other material submitted for publication, they must be typewritten *double spaced* (including references), must not exceed 1½ pages in length and will be subject to editing and possible abridgment.

THE "PILL" AND MYOCARDIAL INFARCTION

To the Editor: Dr. Roth's answer to my letter in *Connecticut Medicine* (Vol. 38, No. 12, p. 669) on 'The "Pill" and Myocardial Infarction' sent me back to statistics. Though individual physicians have prescribed the "pill" earlier, its availability started to blossom in Connecticut after the Supreme Court Decision in 1965.

Just before that time, in 1964, in the age group 15 years to 44, there were 189 male and 35 female deaths from coronary artery disease. This is a rate of less than one female to five males. In the age group 45 to 54 years, there were 584 male deaths and 103 female, again less than one female to five males. This contradicts the findings of Roth, Berki, and Wolff who found only about 1 female in 25 myocardial deaths and of Gerteler and White who found 1 in 33 in the younger age group. It is also at variance with the statement that "the female to male ratio decreases in menopausal women."

I wondered why the female/male ratio in 1972 was 1 to 3 and in 1964 only 1 to 5. These are the findings in some other years:

	Female Deaths	*Male Deaths*	*Ratio Female/Male*
1966 Age Group			
15 - 44	30	161	Less than 1 to 5
45 - 54	134	587	Little more than 1 to 5
1968 Age Group			
15 - 44	33	153	Little more than 1 to 5
45 - 54	137	577	Little more than 1 to 5
1970 Age Group			
15 - 44	26	143	Little less than 1 to 5
45 - 54	132	532	About 1 to 4

These findings enforce the impression that the female/male ratio is about the same in the 15 to 44 and in the 45 to 54 age groups. The ratio is probably nearer 1 to 5 normally. Why the ratio is 1 to 3 in 1972 is unexplained. The findings seem to *indicate again that there is no proof that the "pill" causes myocardial infarction.*

I wonder also why my data are so different from those of Roth, Berki and Wolff and those of Gertcler and White. These researchers used hospital based statistics; mine are those of the Vital Statistics Records of the State of Connecticut. The question arises which are to be preferred if incidence is the important factor. It was found before that hospital data are at a great disadvantage. Hospitals are limited to those patients who come there, and we know that only one in three of the acute myocardial infarcts is so lucky. And there are other myocardial cases which do not get to our acute inpatient institutions. The samples of hospitals are inevitably small and, therefore, statistically less significant; they are also biased. Vital Statistics have their shortcomings also, but in anything concerning incidence of myocardial infarction they seem to offer great advantages.

Gert Wallach, M.D., M.P.H.

Director of Health
Waterbury, Conn.

The above letter was referred to the authors of the article in question who offer the following reply:

To the Editor: I agree fully with Dr. Wallach's statement that hospital statistics are not identical with general vital statistics of the population at large. This is especially the case if these statistics refer to different phenomena. Dr. Wallach quotes vital statistics of death rates of young patients with myocardial infarction while Roth, Berki and Wolff speak about the occurrence rate of myocardial infarction in young people. Incidentally, this occurrence rate is similar to Kagan's et al. Framingham study who found in an eight-year followup of persons between the ages of 30 and 39, that the incidence of coronary heart disease was 24 per thousand in the male population and 1 per thousand in the female population. Given the fact that most patients with myocardial infarction die suddenly outside the hospital and that an even higher proportion of young patients with myocardial infarction die outside the hospital, it is clear that a low percentage of young people with myocardial infarction reach the hospital alive. Of those young people who do arrive at the hospital alive Roth, Berki and Wolff's study of 53 patients with myocardial infarction under 40 years of age found that less than 2% die in the hospital as compared to about a 30% mortality rate in patients with myocardial infarction of all ages. Among the 53 young patients there were only two females and one of them died while none of the 53 male patients died in the hospital.

Two facts stand out in this report: first, that young patients with myocardial infarction who reach the hospital alive usually survive even if they fibrillate in the hospital. This was also shown in the recent report in *Connecticut Medicine* (Vol. 38, No. 12, pg. 669) where all three young women left the hospital alive despite the fact that two of them had cardiac arrest and had to be defibrillated. If these two young women had had ventricular fibrillation outside the hospital, they possibly would have become part of the vital death statistics Dr. Wallach mentions.

Our study and Dr. Spain's study suggests an increased likelihood of sudden death in women who are heavy smokers as compared to male smokers. This possibly could be the reason why among young patients with myocardial infarction, more young females than males die suddenly and less often reach the hospital alive than males. This would explain the fact that the mortality rate in young people with myocardial infarction is less different in females and males in the vital statistics and much more different among those young patients who become hospital statistics after they survive their initial attack.

Another cause of different figures of vital statistics and hospital statistics may be that in the hospital a diagnosis of myocardial infarction is based on strict criteria of typical changes in the electrocardiogram associated with a typical history and enzyme changes diagnostic of myocardial infarction. Vital statistics are often based on the death certificate and many sudden deaths are signed out as myocardial infarction while they may have been due to pulmonary emboli or other acutely, suddenly fatal diseases.

I would also like to mention the fact that at best, statistics are not always fully reliable as the many jokes about statistics and interpretation of statistical figures try to tell us. I would, therefore, like to point out that in our last report, under the discussion, we did not speak of statistics but of three, fortunately still alive, patients. We did not try to prove anything with these three patients and with it two more patients who were later observed. We only tried to draw attention to a possible suspicion of causal connection between "the pill" and a few females who might be unusually sensitive to the adverse effect of the pill particularly if they have other risk factors such as smoking or a positive family history of myocardial infarction at an early age. Though merely a suspicion and of no statistical significance at all, in our opinion this indication warrants taking the warning of chest pain or chest discomfort in young women on oral contraceptives seriously enough to consider discontinuing the pill.

Oscar Roth, M.D.

New Haven, CT.

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POST GRADUATE EDUCATION

To the Editor: In the November, 1974 issue of *Connecticut Medicine*, lists of postgraduate courses offered at Yale University School of Medicine and at Harvard Medical School were printed under "Special Notices." I was pleased to see attention given to all of the courses that are available, but I was very surprised at the paucity of the Yale Listing. Did Yale give you their complete program? I also noted with some concern all of the sponsors of postgraduate courses in the New England area that were not listed.

In Massachusetts our Committee has developed a registry of continuing medical education courses. We have a listing of over 650 courses that are catalogued by subject, date, sponsor and location. We have placed an emphasis on compiling a comprehensive list of courses offered in Massachusetts but we have also included all of New England and some locations elsewhere.

Our early experience with the Registry indicates that there are large numbers of courses and there is considerable interest being expressed by physicians in consulting the Registry. We do not publish lists at this time but rather encourage physicians to call or write our office for a personal response that meets their particular needs. The Registry is also beneficial to course sponsors who want to identify gaps in certain subject areas and who want to avoid conflicting dates.

Based on our experience so far, there is a substantial amount of teaching going on not only in the Boston area, but in many other parts of Massachusetts as well. I would think there is more in Connecticut than those few offered by Yale. I would encourage you, as Editor, to make a more intense effort to identify and list all continuing medical education activity in your state. Physicians are becoming more and more interested in participation and continuing education programs, not only due to external pressures, but because physicians are personally beginning to accept continuing medical education as a life-long responsibility to maintain the quality of care for their patients.

Earle M. Chapman, M.D., Chairman,
Committee on Medical
Education of Massachusetts
Medical Society; Member of
Council on Medical Education
of AMA, 1964-1972.

FLU VACCINE—QUESTION OF INTRADERMAL

To the Editor: Apparently there are Connecticut physicians who continue to administer influenza vaccine via the intradermal route. This method is not recommended by the Viral Diseases Division of the Bureau of Epidemiology of the Center for Disease Control.

The efficacy of intradermal influenza vaccination has been the subject of a limited amount of discussion in the literature during the last 15 years. However, the necessary critical studies have never been done in order to establish the value of intradermal vaccination in large community populations. According to the Center for Disease Control only two small studies performed in 1957 and 1960 showed some efficacy, but not on a large enough scale to be acceptable.

Recent studies reported by the Bureau of Biologics, according to CDC, indicate that antibody levels resulting from intradermal injections are definitely lower than those produced by the subcutaneous and intramuscular routes. The pharmaceutical manufacturers of influenza vaccine do not recommend intradermal vaccinations and advise intramuscular injections. The presently available purified influenza vaccines do not produce the severe reactions which were seen several years ago. Physicians who continue to use the intradermal method should be aware that their patients are not receiving adequate protection against influenza. This method should be discontinued and replaced by the currently recommended and accepted intramuscular influenza vaccine injection.

George Kraus, M.D.

Director of Health,
Greenwich, CT.

SPECIAL NOTICES

SYMPOSIUM

BASIC SCIENCE IN PLASTIC SURGERY—CLINICAL IMPLICATIONS

Co-sponsored by the Educational Foundation of the American Society of Plastic and Reconstructive Surgeons, Inc. and Yale University School of Medicine

APRIL 7-9, 1975

NEW HAVEN, CONN.

Subjects to be covered include: wound healing, transplantation, statistics, infection, flaps and grafts.

ANNUAL MEETING

PLASTIC SURGERY RESEARCH COUNCIL

APRIL 10-11

YALE UNIVERSITY SCHOOL OF MEDICINE

(Harkness Auditorium)

The April 10th morning session will be devoted to current concepts in basic cancer research and the implications for clinicians. The rest of the meeting will be devoted to scientific papers. Special guest speaker: Robert A. Chase, M.D.

President of the National Board of Medical Examiners
"The Implications of the GAP Report"

For information contact:

Thomas J. Krizek, M.D.
Chairman
Plastic Surgery Research Council
Yale University School of Medicine
333 Cedar Street
New Haven, CT. 06510

Medicine in China

Russell B. Roth, M.D.

It is easy indeed to enter the People's Republic of China. One walks a short distance over a covered railroad bridge spanning a narrow stream. A soldier who does not appear the least bit menacing in his baggy blue pants and rumpled khaki blouse holds out his hand for your passport, and, when you have given it to him, that is just about that.

On the other hand, those few steps from LoWu on the Hong Kong side of the bridge to Shum Chen carry one as effectively into a different World as did Alice's steps through the looking glass.

Our American Medical Association emissaries, in July of 1974, were at once sightseers and scientific observers. Our twelve physicians were intrigued by the oft-times differences in American and Chinese management of familiar diseases and disabilities. The conjunction of standard Western scientific approaches with the acupuncture, cupping, moxibustion, and herbal concoctions of traditional Chinese medicine was a constant source of wonderment.

Any understanding of the system and rationale of medical care in China must depend on some degree of understanding of the basic factors governing the character of the People's Republic of China. This does not imply a need for detailed historical study, but it is necessary to recognize that the emergence of a thoroughly communist country of close to 900 million inhabitants has involved a great many departures from the accepted ways of life in the Western World.

Modern Chinese medicine is close to incomprehensible if one attempts to judge it by Western standards.

The striking change in direction of development came in 1949 with the "liberation," in which the forces of Mao Tse-tung, with Marxist-Leninist Communism as the gospel, triumphed over the forces of Chiang Kai-Shek. The Chinese Nationalist Party took refuge in Taiwan, and the People's Republic of China took over the mainland. The first orientation of the PRC was toward Russia and Russian Communism. Medical developments were shaped in the Russian model, and there were efforts to institute 5-year plans in the Russian mode. And then, of course, there developed the Chinese disenchantment with the Communism of Khrushchev and Brezhnev and the estrangement between the two countries. The "cultural revolution" of 1966 really broke all ties between China, Russia and most of the rest of the Western World. The "cultural revolution" was an upheaval which was anti-Western, anti-imperialist, anti-intellectual, anti-science, and pro-traditional Chinese. The Chinese leaders, fellow members of the hierarchy of Chairman Mao, who wished to maintain allegiances with Russia, or who upheld such things as the virtues of Western-type scientific medicine, fell totally out of favor and were branded "revisionists." Two of them, Lin Piao, and Liu Shao Ch'i have been singled out for special attention in campaigns of criticism in which they are called a full range of uncomplimentary names as enemies of the state. Lin Piao died in an airplane crash over Mongolia as he was fleeing to Russia. There are those who assert his plane was shot down by the Maoists. Liu Shao Ch'i is presumably still alive, perhaps in Peking, but certainly in obscurity.

As part of the cultural revolution all of the medical schools were closed, and have only been reopened in the last two or at most three years. In each instance any preexisting primary focus on Western medicine has been changed to a focus on combining Western with Traditional Chinese Medicine. The course has been shortened to three years. Students and faculty alike spend time in the "Country-side" learning from the peasants, and some of their time is spent in manual agricultural farm work to keep in tune with the people they are supposed to serve.

Before judging the appropriateness of this course of development one should remember that, in 1949, there were something over 600 million people in China. There were approximately 40,000 physicians who would be called reasonably well trained in scientific "Western" medicine. They were either graduates of the small number of medical schools in China, or had been educated in the U.S., Canada, or Europe. If one were to pursue the Western approach of making scientific medical care available to all people it would have required training over 500,000 more physicians, and developing the necessary sophisticated and expensive facilities in which they could do their work. And this would need to be done in a turbulent revolution-torn country in which annual average per capita income was well under $100.

DR. RUSSELL B. ROTH, has an active and continuing practice of urology in Erie, PA. In addition, he has devoted much time to organized medicine at the county, state and national level and has served in a number of advisory capacities to Government. He is the immediate past president of the American Medical Association, and as a member of an AMA delegation, had the opportunity to visit the People's Republic of China in July, 1974 as a guest of the Chinese Medical Association.

It was totally out of the realm of remote possibility.

The alternative was to look at the fact that there were some 500,000 herb doctors in the land, largely illiterate, but familiar to the people and in large part trusted by them. It was on them that it was decided to base the system of what passes for medical care in China. For a long time these herbalists and acupuncturists had been in some disrepute. As far back as 1822, during the Ching Dynasty, the Imperial Medical Board considered the contrast between traditional Chinese medicine and the emerging Western science of medicine, and spoke out strongly against the former. Most recently, in 1929, the Kuomintang had outlawed the practice of traditional Chinese medicine as being inappropriate. All this was changed when Mao Tse-Tung announced as one of his four principles in medicine that the objective was to combine Western and Traditional medicine. The basic thrust was to come up with the development of the "barefoot doctor." This is a term rather affectionately applied to a corps, now about 1,200,000 persons strong, who are indeed rarely barefoot and are not to be confused with doctors. They are agricultural workers in the communes, paid as agricultural workers and employed as such, with an assignment in the health care field. They are given three months of education—a little fundamental anatomy, rudimentary physiology, and instruction in how to take a blood pressure, feel a pulse, or read a thermometer. They are familiarized with the signs and symptoms of the commoner ills of their region. They are equipped with a doctor's kit which, in addition to its acupuncture needles and herb medicines, contains penicillin, streptomycin, chloromycetin, digitalis, and many other effective Western-type drugs.

At the other end of the spectrum of medical personnel there are the men and women who were trained in Western Scientific medicine. Many such practitioners, when the chips went down, departed the Country, or, perhaps, were eliminated in one way or another. But many remain, and for them it has become a strong ideological and political necessity to take courses in Traditional medicine, to learn the philosophy of treating the patient instead of the disease, and the techniques of acupuncture, cupping, moxibustion and the like. They are also required to put in time in the "Countryside" which may involve teaching the barefoot doctors, but will also involve physical work alongside the peasants, the workers, and the soldiers. It is fully expected that they will become impressed with the contributions of the traditional techniques in managing many problems as well as, or better than, Western Science. The educational process flows both ways—from professors to peasants and in reverse.

Traditional Chinese Medicine is complex, embracing as it does the use of virtually all available herbs, roots, barks, fruits and flowers, together with a multitude of mineral products and animal derivatives from rhinoceros horn to crushed pearls. These substances and infinite combinations of them are made into powders, potions, decoctions, injectible extracts, and pills. Beyond this there is acupuncture with needles of all sizes and configurations and an infinity of places to insert them, twirl them, twist them, and stimulate them manually or electrically. And then there is moxibustion in which the dried powder of Artemisia plants is burned like punk or like incense, sometimes so as to blister the patient, sometimes not. And to this may be added cupping, usually with bamboo or glass cups, sometimes applied over the acupuncture needles. The problem for the Western-trained mind is to get out of the notion that if one diagnoses the disease process there should be some standardized kind of treatment. Treatment is not primarily directed at the disease. Two patients, each passing comparable ureteral calculi, will be treated quite differently. Two neighbors, each afflicted with the same contagious disease, will be differently managed by the same physician. Treatment is determined by such features as age, sex, occupation, weight, pulse rate, blood pressure, temperature, and recitation of symptoms. Different ingredients are written into the prescriptions, and needles are differently placed and differently handled.

Clearly such infinitely variable therapy is not susceptible to evaluation by double blind techniques. Outcome evaluations are difficult at best. Even as with many of our own therapies it becomes impossible to say whether improvement in the patient is because of or in spite of the management, but we do have ways of standardizing for comparison. There appears to be no disposition to do so on the part of the Chinese.

If one remembers this peculiarly oriental, as against occidental, framework for medicine—part science, part tradition, part ideology—it becomes somewhat easier to fit together the present day facts of medical education and medical practice.

In a sense twelve physicians spending 21 days in the People's Republic of China totalled 252 days of experience and observation in respect to Chinese medical practices. Despite the emphasis placed by our Chinese hosts on acupuncture and traditional Chinese medicine, these did not strike us as being the finest accomplishments of our Chinese colleagues. Our delegation was really far more intrigued by the successes in replanting severed hands, feet, arms and legs, fingers and toes. We were fascinated with the fact that techniques in burn management had succeeded in keeping alive a patient with 99% of his body surface burned, 94% being 3rd degree burns. We felt challenged by Chinese orthopedic concepts of fracture management using short splints with no immobilization of joints. We could not help but be impressed that in a Nation which, thirty years ago, was ravaged by venereal disease and by all manner of other communicable ills, V.D. has essentially been eliminated, and the other transmissible diseases are for the most part under excellent control.

Perhaps too much attention has been paid in the Western World to acupuncture. As treatment it has been well known for thousands of years. It has not provided very satisfactory results for all that time and there is no real scientific evidence that anything on that score has changed. To be sure it has come to play an extremely important part in the Chinese delivery system for health care services, but this is the politico-socio-economic phenomenon which we have discussed.

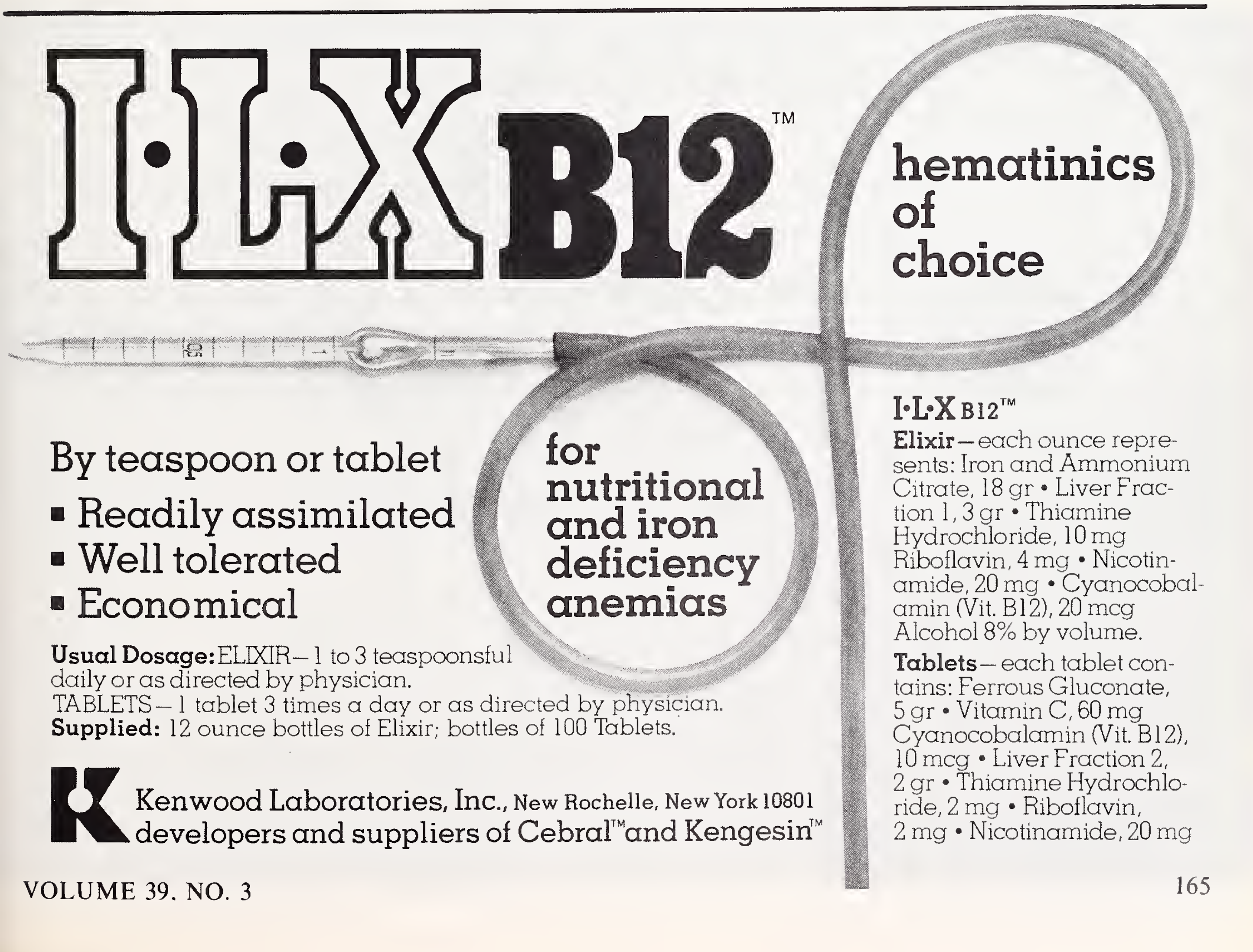
Acupuncture for the relief or prevention of pain, especially during surgery, is new, even to the Chinese. After one has viewed scores of major surgical procedures carried out with acupuncture analgesia alone, or in combination with modern sedatives, narcotics, or anaesthetic agents it is almost impossible to be a disbeliever. Acupuncture, for some surgical procedures on some patients, works superbly well as an analgesic agent. There may be little or no evidence of discomfort. The patient talks, drinks, eats, and cooperates in the procedure. He sits up at the end of the operation, and may well shake hands happily with the visitors to the operating room. We need to try to understand the process.

But it is not all this favorable. It seems clear that pretesting will identify many patients who are not responsive to acupuncture. Some procedures are unsuitable. Acupuncture is actually used in only about 15% of all cases.

It is because acupuncture and the other elements of traditional Chinese medicine seem to be more substitutes for good scientific medical care than contributions to it, that one should not become preoccupied with them. It could lead to a serious misconception of the competence of Chinese medical care.

In terms of ultimate therapeutic results, if one were so unfortunate as to be horribly burned, or to suffer a severely fractured femur, or to have a traumatic amputation of an arm, it would not be bad to have it happen in China—at least in close proximity to Peking, Shanghai, Kwangchow or one of the other medical centers. There might be many many short-

Continued on Page 184



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A Report to the Profession from the Breast Cancer Task Force

Breast cancer is the major cause of death due to cancer among women in the United States. This year there will be an estimated 89,000 new cases and 32,500 deaths from breast cancer in this country.

Because of this grave health problem and because the extent of traditional surgical treatment for the disease has been questioned, a sustained effort has been mounted by the National Cancer Institute's Breast Cancer Task Force to improve the diagnosis and treatment of this dreaded disease.

What has emerged from this effort and is here reported, is a significant step forward in earlier diagnosis and more effective treatments for both localized and advanced disease. It should be emphasized that these findings are tentative and do not, by themselves, represent major breakthroughs. More time and more study will be needed to document long-term results and to improve our techniques.

However, it should also be emphasized that encouraging trends have emerged from enough different studies to justify confidence in the preliminary findings. In short, we know that it is best to find breast cancer in its earliest, and therefore most curative stages. In cooperation with the American Cancer Society, we have demonstrated a significant improvement in our capability to accomplish this goal. At the same time there is preliminary evidence that more effective treatments have been developed for both early and advanced disease. If this evidence is sustained by the passage of time, and we have confidence that it will be, it should be possible to improve substantially both the cure and survival rates from cancer of the breast, and with less disfiguration than results from radical mastectomy.

Breast Cancer Detection

Early detection of breast cancer before it has spread to other parts of the body increases a patient's chance for long-term survival and cure. Patients whose axillary (armpit) lymph nodes are free of cancer (negative nodes) at the time of breast cancer diagnosis have a 5-year survival rate of about 75 percent, and about 65 percent of these patients are alive after 10 years. In contrast, women with breast cancer in the axillary nodes (positive nodes) have a 5-year survival rate of about 50 percent, and only about 25 percent will live 10 years.

In the U.S. at present, patients have negative, cancer-free nodes in about 45 percent of newly-diagnosed breast cancer cases. A real hope that this rate may be improved—with a corresponding increase in survival rates—comes from the breast cancer screening demonstration program sponsored jointly by the ACS and the National Cancer Institute. Dr. William Pomerance, Chairman of the Breast Cancer Task Force's Diagnosis Committee, reported that about 75 percent of the women with breast cancer, detected so far by the screening program, had negative nodes.

The ACS-NCI program involves 27 breast cancer screening projects, where up to 270,000 women of ages 35 and older will be screened annually with a physical examination, X-rays (film mammography or xeroradiography), and thermography. The first projects established began screening women in mid-1973; all 27 centers will be operating by the end of 1974. About 75,000 women have been screened to date. When comprehensive data have been compiled, it is expected that about 775 breast cancers will have been detected among these women, a rate of 10.5 cases per 1,000 women screened, or about 1,000 cases per 100,000 women screened.

The combination of physical examination and X-ray mammography in breast cancer screening has been shown to decrease breast cancer death rates. A group of 31,000 women screened for breast cancer by the Health Insurance Plan of Greater New York in a NCI-supported study have had a one-third reduction in breast cancer deaths over a 5-year follow-up period as compared with 31,000 women given their usual comprehensive medical care in their medical groups. One-third (44 out of 132) of the breast cancers detected in the screening program were found by X-ray mammography before the tumors were large enough to be detected physically. Only one of these 44 women died of breast cancer during the 5-year period, indicating that early detection led to substantially more effective treatment.

Breast Cancer Treatment

Breast cancer presents usually as disease limited to the breast and axillary nodes without clinical evidence of metastatic disease. Surgery has been the main weapon against cancer of the breast for the past six or more decades. The standard approach to surgery has been radical mastectomy. Radical mastectomy means removal of the breast, underlying pectoral muscles and axillary lymph nodes.

From the Department of Health, Education, and Welfare, Public Health Service, National Institutes of Health, Bethesda, Maryland.

Recently, less radical procedures have been recommended, but supporting data from controlled clinical studies have not yet been available in the United States.

Primary Breast Cancer

Dr. Bernard Fisher of the University of Pittsburgh, Chairman of the National Surgical Adjuvant Breast Project (NSABP), has directed a large clinical study involving surgeons, radiotherapists and pathologists at 34 institutions attempting to determine the optimal treatment for primary breast cancer. This study, supported by NCI grants and the Breast Cancer Task Force, has involved 1,700 patients.

For patients with operable disease limited to the breast, the study compares radical mastectomy, total mastectomy (removal of breast only), and total mastectomy plus radiation therapy to the chest. For patients whose disease involves the breast and axillary nodes, radical mastectomy is compared with total mastectomy combined with postoperative radiotherapy.

The results after two years indicate that in each group the various options are essentially equivalent. Thus, for disease limited to the breast, a total mastectomy with or without radiation therapy is equivalent to the radical procedure. For patients with disease in the breast and axillary nodes, total mastectomy with postoperative radiotherapy is equivalent to radical mastectomy. While the long-term follow-up data necessary to obtain survival characteristics are not yet available from this study, similar trends from early stages of other studies have been borne out by long-term follow-up and are thus considered predictive. The major impact of these results is to provide scientific information for practicing surgeons to determine the most effective type of operation for each patient and, in addition, to set the stage for planned clinical studies of less surgery (segmental mastectomy), a procedure where only part of the breast is removed.

Early Chemotherapy

Historically more than 50 percent of breast cancer patients die with metastatic disease. Previous studies have indicated that the presence of cancer in the axillary nodes carries a dire prognosis. More than 75 percent of patients with one or more positive nodes will have recurrent disease at 10 years and most of the patients will die of their disease. Thus, the presence of axillary gland involvement predicts the presence of metastatic disease.

To combat this clinical situation a second study, sponsored by the Breast Cancer Task Force and done jointly by the NSABP and members of the Eastern Cooperative Oncology Group and the Central Oncology Group, is investigating the addition of postoperative systemic chemotherapy in women who have had modified or radical mastectomy and shown to have positive axillary nodes. To date 250 patients have been entered on a double-blind randomized study receiving either a placebo or L-phenylalanine mustard (L-PAM), an oral anticancer drug, for five days by mouth every six weeks for two years.

The study has been underway about 24 months and involves 37 institutions. Data concerning the results of the study to date, presented by Dr. Fisher, have been analyzed independently by Dr. Carole Redmond of the University of Pittsburgh and Dr. Marvin Zelen of the Statistical Laboratory of the University of New York at Buffalo. The data indicate that the recurrence rate is significantly reduced for women receiving the L-PAM. This was particularly striking for women who were premenopausal where only 1 of 30 patients receiving L-PAM recurred, whereas 11 of 37 recurred after surgery alone. The investigators have recommended that the study be terminated for the premenopausal group of patients because of these dramatic results. For postmenopausal patients the failure rates are also reduced in the L-PAM treated group, but not as markedly. For this reason, that part of the study involving postmenopausal women is under further review.

Dr. Paul P. Carbone, Chairman of the Breast Cancer Task Force Treatment Committee, also reported that similar studies employing combination chemotherapy regimes are being done at the National Cancer Institute of Milan, Italy, the Mayo Clinic, the University of California at Los Angeles, and the Cleveland Clinic. The study at the Milan Cancer Institute has accrued 100 patients who are receiving the three-drug combination of cytoxan, methotrexate and 5-fluorouracil. Results are consistent with the L-PAM study.

The importance of these postoperative chemotherapy trials is that patients with breast cancer and axillary node metastasis can receive drug therapy to treat the subclinical metastases before they become clinically obvious and lethal. From two previous clinical studies and from experimental data in animals, this combined approach of surgery and chemotherapy offers the best chance of survival.

The L-PAM treatment is a simple program with minimal side effects and can be widely used. With these encouraging results Dr. Fisher and the NSABP investigators are planning an additional study using a two-drug combination and a combination of L-PAM with C. Parvum, an immunostimulant.

Advanced Disease

Dr. Carbone reported preliminary results from several other studies of patients with metastatic disease indicating that combinations of drugs are more effective than single drugs. In a study sponsored by the Eastern Cooperative Oncology Group a three-drug combination produced 53 percent response (shrinkage of tumor by 50 percent or more) as compared to 19 percent with L-PAM alone. Patients receiving the combination regime had more complete responses and longer survivals than patients treated with the single agent.

Similar improved results with combination therapy are reported in a study by Dr. David Ahmann and his co-workers at the Mayo Clinic. Drs. John Horton, the Albany Medical College of Union University, and Thomas Dao, Roswell Park Memorial Institute, have reported improved results with the combination chemotherapy of cytoxan, fluorouracil and prednisone as compared to adrenalectomy and adriamycin alone.

Dr. Douglass Tormey and co-workers at the National Cancer Institute, have demonstrated improved results by incorporating adriamycin into a three-drug combination using cytoxan and fluorouracil.

In several ongoing research studies, immunostimulants such as BCG and C. Parvum are being added to chemotherapy to determine whether treatment results can be improved.

While management of the advanced disease patients has improved, the likelihood of eliminating all cancer cells is highest when the numbers of cancer cells are small. This is most likely to occur when the patient first presents with cancer. An objective of the Breast Cancer Task Force is to develop therapeutic programs utilizing effective local treatment in combination with safe, easily administered systemic anticancer drug combinations.

Hormone Receptors

Removal of the ovaries in premenopausal women and the removal of the adrenals or pituitary are forms of breast cancer therapy to which approximately 30 percent of women respond. Administration of androgens or estrogens can also induce tumor regression. These responses occur in 20 to 40 percent of patients.

Dr. William McGuire, of the University of Texas at San Antonio and a member of the Breast Cancer Task Force Treatment Committee, described the role of hormone receptors (specific cell proteins) in predicting response to these endocrine treatments for breast cancer. The laboratory determination of whether an individual patient has a hormone receptor can be used to predict whether she will respond to hormone therapy. The importance of this test is that it differentiates between patients who would benefit from hormone therapy and those who would not. These latter patients can then be placed on other therapies without delay.

Approximately 50 percent of biopsies of breast cancer are found to contain the receptors. The response rate to endocrine treatments by patients with positive endocrine receptor (ER) tests was markedly higher than that in ER negative patients. For ER positive patients 52 percent responded compared to 4 percent responses in patients who were ER negative. Thus the estrogen receptor assays can be helpful to predict the results of endocrine therapy and increase the likelihood of predicting response. The challenge of the future is to incorporate endocrine therapy into the treatment strategy with chemotherapy for those patients who are ER positive. For the ER negative patients two approaches appear possible. These patients can be treated directly with non-hormonal methods obviating the delay of less effective measures. Secondly, there may be ways to uncover or alter the hormone receptors to make them sensitive.

Several studies are being sponsored by the Breast Cancer Task Force to combine hormonal approaches with chemotherapy. Two studies, one at the Mayo Clinic and the other through the Eastern Cooperative Oncology Group, are studying ways to combine combination chemotherapy with oophorectomy in premenopausal women. Another approach being done at Emory University by Dr. Charles Vogel combines estrogens with a three-drug combination of cytoxan, fluorouracil and adriamycin.

Dr. Tormey, Chief of the NCI Medical Breast Cancer Service, reported on studies of biologic markers—substances found in the blood or urine that correlate with the presence of tumor. Ideally, levels of these substances should correlate with the amount of tumor in the patient and change in parallel with the response of tumors to therapy.

Out of the eight biologic markers tested, three, human chorionic gonadotrophin (HCG), carcinoembryonic antigen (CEA), and a transfer RNA nucleoside (N^2N^2-dimethylguanosine), were found to be present in abnormal amounts. Using these markers, 63 patients (97 percent) in a group of 65 were found to have abnormal levels of at least one of these markers. In a group of 15 post-operative patients found to have positive nodes, 10 (67 percent) had elevated levels.

Summary

At the present time, the two-year report from the Breast Cancer Task Force indicates that less than radical surgery is acceptable for the treatment of primary breast cancer. Moreover, the trends of other studies involving surgery and chemotherapy for women with breast cancer and positive axillary nodes show that the recurrence rate can be significantly reduced. This in turn indicates that we can successfully treat sub-clinical metastasis. The advances in the treatment of early and advanced breast cancer, coupled with progress in earlier detection and diagnosis, should lead to significant improvements in cure rates and survival.

It should be emphasized that this report does not include results from other research studies conducted by the NCI, cooperative groups and individual institutions.

SPECIAL NOTICES

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Department of Continuing Education

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GENERAL SURGERY
APRIL 28 - MAY 16, 1975

at the
MASSACHUSETTS GENERAL HOSPITAL
Under the Direction of
W. Gerald Austen, M.D., Glenn E. Behringer, M.D., and George L. Nardi, M.D.

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This course is accredited on an hour by hour basis toward the AMA's Physicians' Recognition Award.

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Understanding Modern Immunology:
I. The Development of the Human Immune System

(First of Two Parts)

John M. Dwyer, M.D., Ph.D.

No area of clinical science has progressed more rapidly than Immunology. Consequently, it has not been easy to keep up-to-date with either the factual or conceptual advances of this discipline. However, like a giant jigsaw puzzle, at last the pieces of information gathered from all over the world can be locked together to present a coherent picture of one of nature's most fascinating complexities. Physicians today can no more escape the emergence of the lymphocyte into "T" and "B" cells than they can escape prostaglandins; both are here to stay. The rewards from grappling with modern immunology are not only academic. With all due care, immunological knowledge is being increasingly applied to clinical problems. Thus, immunotherapy for cancer is becoming increasingly important and it seems certain that the recognition and management of diseases associated with immune-complex depositions will rapidly improve as more physicians become comfortable with the pathogenesis involved. The immunology of transplantation is encroaching into preventative medicine, as well as speeding us to the goal of better organ transfers. Immediate hypersensitivity phenomena, serum sickness, vaccination procedures, the management of immune deficiencies, and auto-immune diseases are but some of the problems that require an understanding of basic immunological mechanisms before today's physicians can approach them competently. What is the best way of coming to grips with all of this new knowledge, with all of the scattered pieces of the immunological jigsaw puzzle? It is this author's opinion that understanding the way the immune system develops, and the biological functions it is required to play, simplifies clinical immunology to the point where one can readily predict the aberrations and the management of immunological problems. Based on this concept there follows a description of the birth, life and death of lymphocytes, those sophisticated cells who supply us with a protective system that has a "brain" rather than the non-discriminating phagocytic system of the more primitive species.

The Development of the Humoral Immune System

The story begins in the human fetus between the sixth to eighth week of fetal life. At this time, there are numerous cells present in both the yolk sac and the liver (Fig. 1) which can be regarded as pluripotential; cells which given the appropriate educational experience (micro-environment) can mature to become platelets, monocytes, etc. Of special interest in our context are the stem cells that will become lymphocytes. At about eight weeks of fetal life some of these stem cells enter the bone marrow.

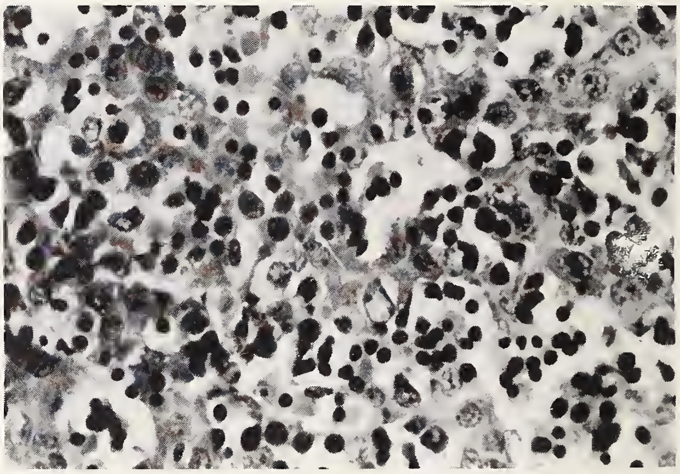

Figure 1

Human fetal liver at 8 weeks of gestation. Note the large number of stem cells present.

The currently available evidence strongly suggests that it is here that the stem cells can develop into lymphocytes, cells which we know are educated to supply us with a humoral immune system (antibody producing system). These lymphocytes are known as "B" lymphocytes, or "B" cells, because they come from the bone marrow. It is a fortunate linguistic co-incidence that the anatomically distinct Bursa of Fabricius, the organ in birds that produces lymphocytes for the humoral immune system, also starts with a "B".

Now it is important to understand what happens to that stem cell in the bone marrow that qualifies it for B lymphocyte status. We do not know the full story but we do know that the education process is directed by a complex genetic mechanism and we understand some of the skills taught these cells. Perhaps the most difficult concept in all immunology must be grasped at this point. The fundamental skill taught each of these cells is the ability to recognize with exquisite sensitivity, one and only one antigen.[1] That is, each B lymphocyte is given the necessary

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apparatus to allow it to recognize a specific antigenic determinant, a specific chemical and steric configuration that it can recognize. Despite the fact that Ehrlich predicted such a specificity before the turn of the century, the conceptual problems of his theory prevented scientists from considering it seriously until the past few years. The conceptual problems were obvious. To have one lymphocyte recognizing one antigen would require the existence, in an antigen-free fetus, of some great biological check board upon which was listed all of the antigenic structures we need to recognize. Also needed would be an assembly line foreman to assign a given number of lymphocytes to each antigen and then place a tick on the board beside that antigen, moving the production line onto the next custom built model. Today we know that this is the type of system employed. We are thus born with relatively few lymphocytes that can recognize any given antigen and many, indeed, most lymphocytes, will never meet "their" antigen. We do not know how nature does all this but we do know how these cells recognize antigens. As stem cells are maturing to "B" lymphocytes, they are taught to manufacture and attach to their cell membrane a recognition molecule. As is entirely appropriate for a system whose definitive function is to produce antibodies, this recognition molecule is itself an antibody.

All antibodies are gammaglobulins, so-called because in an electrophoretic strip those globulins with antibody properties, immunoglobulins, migrate to what is called the gamma region. The basic structure of these immunoglobulins consists of two heavy and two light chains of amino-acids joined as shown in Fig. 2 by disulfide bridges. The molecule can be split in half by the enzyme, papain, and we know that the two halves of the molecule have different functions. Thus, one fragment of the whole molecule (Fab) contains the antibody activity; that is, the ability to bind to a specific antigen. The specificity is a result of a specific amino-acid sequence and a three dimensional shape inherent in the terminal sections of this Fab fragment. The other half of the molecule, of Fc fragment (so-called before its function was clear because it tended to crystallise), determines what the antibody can do once it has bound its antigen. Can it ignite the complement system, can it bind to mast cells, or basophils, can it cross the placenta, etc.? All of these properties of the molecule as a whole are determined by its Fc fragment. Depending on the arrangement of this end of the molecule, we can divide antibodies into five classes known as IgM, IgG, IgA, IgD, and IgE.

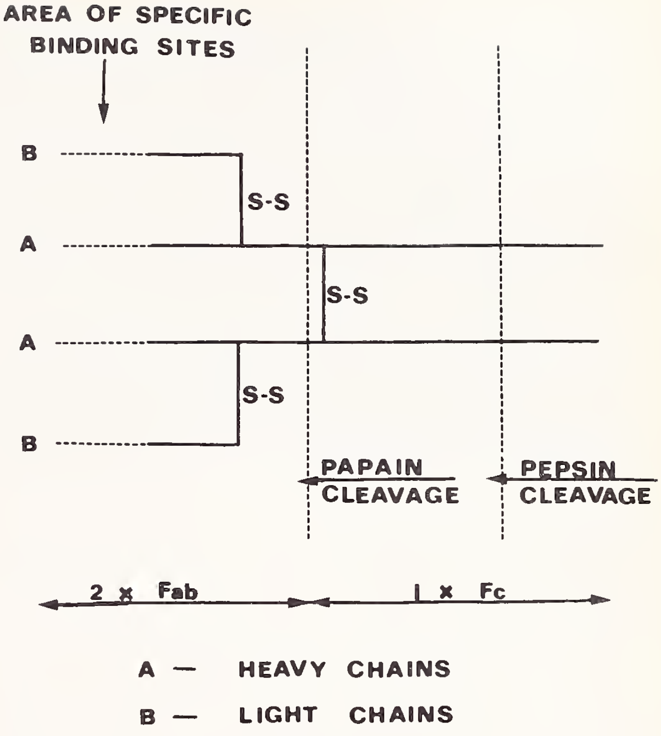

Figure 2

Basic structure of an antibody. Two heavy and two light chains of amino acids joined by disulfide bridges. The dotted areas of the Fab fraction represent the sites where antigen may bind.

Now returning to the "B" cell antigen recognition site, it seems certain that "B" cells learn to manufacture and attach to their surface membrane antibody molecules with their Fc fragment buried in the cells plasma membrane, and the Fab fraction probing away from the cell surface ever alert for the antigen that will match its combining site. We are used to looking at pictures of lymphocytes made from blood smear preparations where these cells look anything but dramatic. Recent pictures taken with a scanning electron microscope reveal a much more interesting anatomy. "B" lymphocytes have projecting from their surface enumerable protrusions giving these cells an enormous surface area on which to attach their recognition or receptor molecules. (See pictures in New England Journal, *289*:548, 1973).

If "B" cells emerge from the bone marrow with antibodies on their surface, what class of antibody is involved? The answer is of clinical as well as academic importance. The virgin "B" lymphocytes have antibodies of the IgM class on their surface. IgM in the serum tends to form a pentamer, five monomeric units joined together at the terminal end of the Fc fragments. On the cell membrane it seems the antibodies are in their monomeric form. From eight weeks of fetal life the bone marrow graduates millions of these receptor bearing lymphocytes which are ready to encounter antigen from that moment, but remain idle during fetal life due to the sheltered environment. Should an intrauterine infection occur, however, and the fetus be exposed to antigen, it can respond even at this early stage of life. What does this response involve? When a "B" lymphocyte binds antigen to its surface it is triggered into action by surface energy changes which activate the cyclic 3, 5 GMP/AMP system and promote electrolyte changes across the lymphocyte membrane. The end result is the triggering of the cell to synthesise protein, RNA, DNA, and divide. Some "B" cells when they divide become plasma cells. The latter are factories producing 2,000 molecules/second of antibody specifically directed against the antigen that triggered the receptor on the B cell from which the plasma cell was derived. What could be more logical than that the plasma cell produce and secrete vast amounts of the same antibody that was on the surface of the B cell which successfully trapped the antigen. Consequently, as most of our original B cells have IgM receptors, the primary immune response largely consists of the production of IgM antibody.

Some B lymphocytes when triggered by antigens divide to produce more of themselves—memory cells. We thus expand the family, or clone of cells, that is capable of reorganizing a given antigen ensuring that the next time that we meet that antigen a brisker response will follow. In the production of these cells, however, a subtle but important change occurs. Again, under genetic control, the class of the antibody that makes up the receptor material on the surface of the memory cell changes to IgG. Thus, the plasma cells derived from this clone of cells will produce IgG antibodies. Memory cells from a further encounter may have IgA on their surface. It thus seems that at least as far as serum immunoglobulins are concerned we can produce IgM, then IgG, then IgA, in that order. We are not sure at this stage where IgE and IgD fit into such a scheme. It was in the primitive sharks that nature first evolved an antibody producing system and these species could only produce a primitive form of IgM.

The clinical implications are important. Vaccinations with antigens initially produce the relatively clumsy, relatively short-lived IgM antibody. Booster doses produce increasing amounts of IgG, a longer-lived and more useful antibody. Primary immune deficiency states include developmental anomalies such that lymphocytes cannot differentiate past the IgM and IgG stage leading to IgA deficiency, etc.

The IgA System

If skin is the chief protector of our exterior surface, IgA is the chief protector of our interior. From mouth to anus IgA plays a vital role. The gut associated lymphoid tissue contains B lymphocytes whose major function is to produce plasma cells secreting IgA, an immunoglobulin ideally suited to this environment. IgA secreted by these plasma cells is in the form of a dimer, i.e. two basic antibody molecules joined together in a V-shape in contradistinction to monomeric units which consist of one basic antibody molecule. In this V-shaped dimeric form IgA can link up with a special molecule produced by the intestinal epithelium called secretory components (SC)[2] which tightly wedges itself into the base of the V of the IgA molecule. When secretory component has attached itself to IgA, it greatly facilitates its passage from the base of the intestinal crypts where it is produced, to the mucosal surface where it is needed. There is much evidence to suggest that B lymphocytes with IgA receptors tend to "home" to the gut associated lymphoid tissue and this secretory IgA system may develop independently from the serum IgA system. There is more IgA in saliva than serum at birth. The humoral immune system is well developed by the 16th week of fetal life at which stage B lymphocytes are either sequestered in lymphoid tissue or are circulating in blood or lymph.

The Development of a Cell Mediated Immune System

Returning to the eight week old human fetus with its pluripotential stem cells in yolk sac and liver we can follow the course taken by stem cells destined to supply a second weapon system for specific immunity—the cell mediated immune system (CMI).

While the stem cells have been developing the thymus gland has been forming. This gland originates from the third and fourth branchial pouches together with the parathyroid glands and some of the structures that will contribute to the great vessels of the heart. Down through the neck these structures come to overlay the great vessels emerging from the heart by eight weeks of fetal life. The thymus is a bilobed structure and within its microenvironment some of the pleuripotential stem cells will become lymphocytes—"T" lymphocytes, or "T" cells, so-called because they are derived from the thymus, Fig. 3. The stem cells begin their education in the cortex of the gland and as they mature they progress to the medulla of the gland. In preparations for light microscopy "T" and "B" lymphocytes are indistinguishable; a pity, as they are as different as polymorphs and platelets. With the scanning electron microscope T cells appear "bald" in comparison to "B" lymphocytes as they do not have projections from their surface. (See New England Journal, *289:* 548, 1973).

As with the "B" lymphocytes, so the "T" lymphocyte has to learn how to recognize a given antigenic determinant. As far as we know, nature uses the

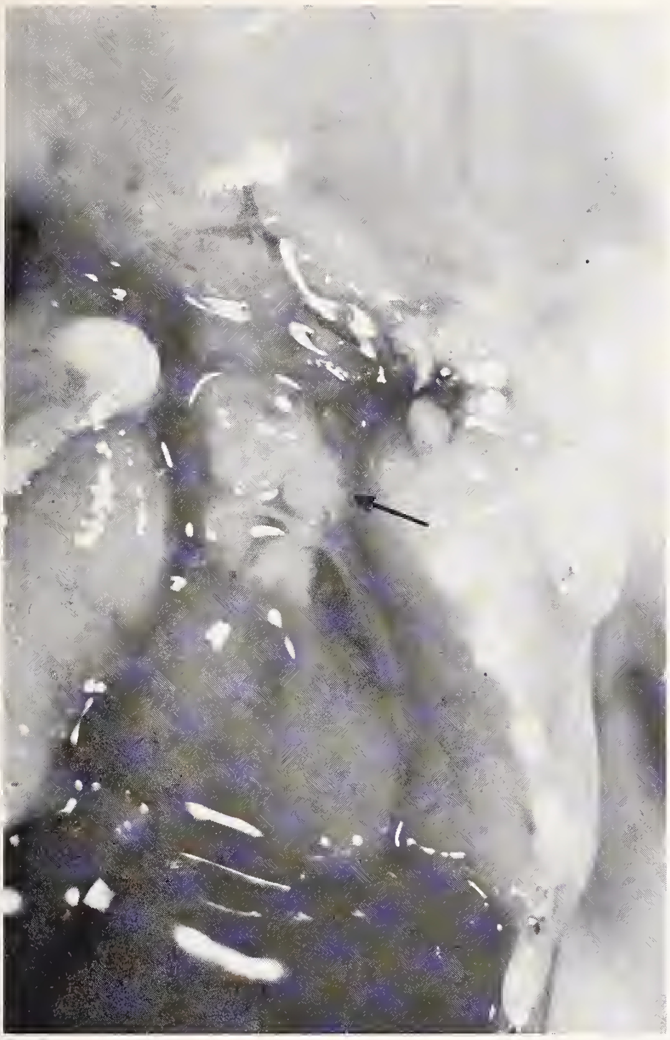

Figure 3
Mediastinum of 11 week human fetus. The thymus (arrow) is a bilobed gland overlaying the great vessels of the heart. Here stem cells become T lymphocytes.

same system detailed for the B lymphocyte. Certainly, T lymphocytes are equally as sensitive and specific in recognizing antigens. There is, however, perhaps a thousand-fold less immunoglobulin on the surface of a T cell than on a B cell, and this has made their receptors harder to study.[1] Some immunologists are confident this receptor material is IgM while others feel it is an immunoglobulin of unique class (? IgT). What is certain is that the basic system of having cells with antigen recognition units affixed to their surface is utilized here as in the B cell system. Thus, as T cells leave the thymus they will respond to physical contact with "their" antigen by initiating not antibody production, but a CMI response. (Fig. 4)

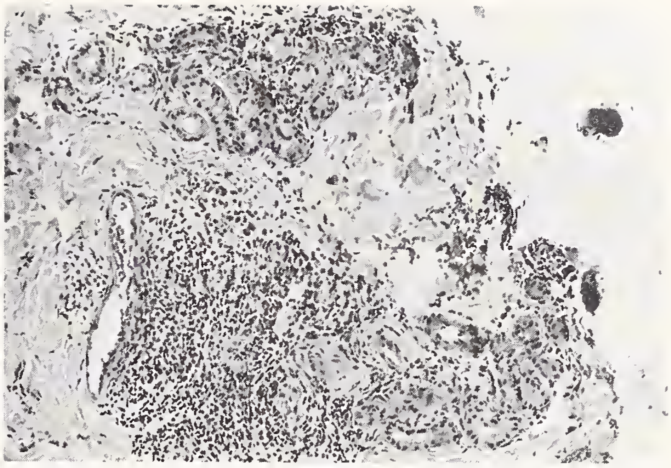

Figure 4
Histology of a CMI reaction. Here, in response to intradermal tuberculin, T lymphocytes have recognized this antigen and over 48 hours have attracted from the nearby blood vessels many lymphocytes and macrophages to help produce the inflammatory response seen here and known as delayed hypersensitivity.

The term CMI is descriptive but does point out the essential feature of this system. The T cells themselves bind antigen and then release a host of pharmacological factors called lymphokines which produce a specific inflammatory response that leads to the elimination of antigen. This reaction is called delayed hypersensitivity and is visualized in the skin when one sees a positive tuberculin test, or its equivalent. T cell reactions also lead to the formation of memory T cells that ensure more efficient secondary immune responses. Thus, specific immunity is in the hands of two classes of lymphocytes; one bone marrow derived, one thymus derived. These cells manufacture and attach to their surface an immunoglobulin receptor that enables them to recognize a specific antigen. As there are relatively few of these cells that can recognize any given antigen the primary immune response is slow and relatively inefficient. The memory cells produced by the initial encounter with antigen ensure both a more rapid and more sophisticated secondary immune response.

Non-reactivity to Auto-antigens

Another conceptual problem to be overcome in accepting the fact that a fetus could be armed to recognize thousands of antigens not present in its body was the matter of distinguishing self fron nonself. How could the immuno-regulatory genes program in recognition capacities for foreignness and program out recognition capacities for self-antigens. We know that non-reactivity to self-antigens is a reality at least in the clinical sense that auto-immune disease is the exception, not the rule. In the immunological sense non-reactivity to self seems to rely on a T lymphocyte phenomenon. During the first few weeks that the immune system is developing, antigen recognition units that will allow the recognition of self-antigens are generated. However, in the case of the T lymphocyte, encountering these antigens, leads not to an immune response but to a prolonged state of immunological paralysis. The T cells so paralyzed remain in the body but are inactive. Thus, CMI reactions against our own tissues are prevented. This paralysis can be reversed with resulting autoimmune disease. It has been demonstrated in animals that the introduction of foreign antigens into fetal tissues during the formative stages of the immune apparatus will lead to an adult state of non-reactivity to those antigens. "B" lymphocytes do not become paralyzed in the same way. They can and do make small amounts of auto-antibody but in order to make dangerous amounts of auto-antibody, B cells that can recognize self-antigens require cooperation from the corresponding T cells. As the latter are paralyzed the immune response against self is effectively blocked. Why not paralyze the B cells as well as the T cells? It seems that the dichotomy was a purposeful evolutionary step as small amounts of auto-antibody may actually help in the maintenance of T cell non-reactivity to self. These antibodies may form complexes with tissue antigens and hide their antigenic determinants from T cell recognition units. These so-called "blocking" antibodies, although directed against self-antigens, may play a vital role in the maintenance of non-reactivity to self.[3]

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Expulsion from Medical Society

Angela Roddey Holder, J.D.

A professional association, like a country club or other such organization, is considered to be a "voluntary association" and as such under general legal principles would presumably be free to conduct its business as it sees fit without interference from the courts. In recent years, however, courts have held that because members of medical societies, bar associations or similar groups derive both directly (referrals from other members of either patients or clients) or indirectly (increased professional prestige) actual economic benefit from their membership, the applicant for admission to the group may be able to show economic loss from his exclusion. Thus at least for the past 15 years courts have held that he may not be denied admission for arbitrary or capricious reasons or those unrelated to professional competence and qualification.

Professional associations usually have a constitution and bylaws and both are required if the group is incorporated. Members, once accepted, are conclusively presumed to know the applicable regulations and may be penalized by the association for disobedience to them.

Courts do assume that a member of a professional association does have a property interest in his membership in the sense that expulsion will have an adverse effect on his practice. Thus disciplinary actions must be "fundamentally fair" since the accused's professional reputation may be at stake. The grounds for action against a member must be reasonable; for example, legal but unpopular political activity would not be acceptable as a ground for expelling a member.

Procedural Problems

The procedures used for expulsion must also be fair. Bylaws must provide for procedures to be followed in case of complaint against a member and these provisions must be followed precisely.

Beyond the bylaws, moreover, the constitutional requirements of due process of law give the accused member certain basic rights even if the bylaws do not require them. He must have adequate notice of specific factual charges against him and a general charge of "unprofessional conduct" or similar vague allegation without notification of the facts on which the charge is based is legally insufficient. He has the right to a fair and impartial hearing at which he has the right to appear and defend himself and present any witnesses he chooses to offer. There are no decisions to date on the right to counsel at a disciplinary hearing but should appearance of an attorney be denied, it is highly improbable that any court would rule that due process had been observed. Further, most cases indicate that administrative appeals to a higher-level body, such as the state medical society, must be provided. Under normal circumstances, in which the disciplined member cannot prove that administrative appeals are established in such a way as to be basically unfair or useless, he must exhaust his administrative appeals before a court will review his complaint.

Grounds for Expulsion: Criminal Conduct

In general courts seem to take the position that grounds for expulsion from a professional society must constitute violation of the criminal law, whether or not the criminal activity is in any way related to the member's professional practice or the activity, if non-criminal, must constitute unprofessional conduct of a very serious nature and have occurred during professional activities. For example, a large number of medical society expulsion and license revocation cases involve physicians convicted of tax fraud and evasion although the evasion does not necessarily involve failure to pay taxes on income derived solely from the medical practice. Courts unanimously hold that tax fraud or evasion is "a crime involving moral turpitude" and uphold the expulsion or revocation.

On the other hand, non-criminal fraud must, in order to support professional disciplinary action, be related to professional activities. Fraudulent misrepresentation of a patient's condition to induce the patient to undergo unnecessary surgery solely for the financial benefit of the surgeon would certainly be considered sufficient by any court to justify disciplinary action; fraud by the physician in the sale of his house would not.

Conviction of any serious crime will undoubtedly justify professional disciplinary action and recent decisions involve expulsions on the basis of convictions for counterfeiting, tax fraud, homosexual offenses and other felonies totally unrelated to professional behavior. On the other hand, a technical felony which does not necessarily involve moral turpitude, such as serving alcoholic beverages to minors, does not. There are no decisions involving any attempts to enforce disciplinary measures after

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conviction of serious but non-felonious offenses such as driving while intoxicated but in that case in the absence of bodily harm in an accident it is unlikely that such an attempt would be successful.

Acquittal of a felony is not necessarily a bar to subsequent disciplinary actions since courts view license revocation or expulsion proceedings as attempts to protect the public from the unfit or incompetent, not as punishment for the professional person. Therefore constitutional prohibitions against double jeopardy are held not to apply. Where this occurs, however, presumably the crime charged must have been related in some manner to professional activity since the disciplinary action must be based on "unprofessional conduct," not a criminal conviction. The only cases which can be located involving judicial review of actions taken by medical societies after physicians were acquitted of criminal charges by juries were cases in which the physicians had been charged with performance of illegal abortions and presumably the same professional-activity connection would be required in any other situation following an acquittal.

It should be noted in this regard that disciplinary actions are civil actions and the burden of proof that the acts were in fact performed is discharged by proof to the civil standard: that it is more probable than not that the charges are true. Before a criminal verdict may be given, of course the facts must be proved beyond a reasonable doubt. It is therefore altogether possible that an activity undertaken in the course of professional practice may not be provable to the extent necessary to sustain a guilty verdict at a criminal trial but be proved to an acceptable degree at a disciplinary proceeding.

A guilty plea, of course, is equated with a conviction after a trial. Furthermore, a plea of "nolo contendere" is considered to constitute a plea of guilty both for purposes of criminal sentencing and for disciplinary measures. For example, after former Vice President Agnew pleaded nolo contendere to one count of tax evasion he appeared on television to point out that he had not pleaded guilty, from which it could be inferred that there was supposedly some question as to any admission of wrong-doing. The Maryland Supreme Court quite correctly pointed out in its decision upholding his permanent disbarment that "nolo contendere" is an admission of the facts to the same extent as a guilty plea. The only difference between the two is, in fact, that in any subsequent civil action (i.e. a suit by the government for payment of taxes due) a plea of nolo contendere may not be used as an admission of civil liability and the amount due must be, in these cases, proved anew. For disciplinary purposes as well as criminal sentencing, therefore, a jury finding of guilt, a guilty plea and a plea of nolo contendere all have the same effect.

Grounds for Expulsion: Non-Criminal Conduct

Professionally unethical but non-criminal conduct is ample ground for disciplinary action. Advertising, for example, of one's professional services in newspapers would be entirely adequate to support expulsion from a professional society. Preparation of false medical reports for use in personal injury litigation even though the falsification does not involve facts on which a perjury charge can be maintained has been accepted in numerous instances as sufficient to justify expulsion or license revocation both for the physician and the attorney involved in the cases. Sexual misbehavior with patients even though it does not constitute rape or statutory rape or any other criminal offense is also sufficient.

The myriad varieties of examples of unprofessional conduct which can be located in court decisions upholding disciplinary actions are absolutely astounding, ranging from sale of answers to State Board examinations to sexual intercourse with a patient under anesthesia. In summary, however, any serious breach of stated or implied ethical standards is acceptable as a justified ground for disciplinary action.

In general courts will not disturb a finding that a given set of facts do constitute "unprofessional conduct" since that is normally considered a judgment to be made by professional peers applying the standard of the appropriate profession and not a matter for judicial review. However, activity which is clearly legal and protected by the Constitution, usually in fact cases involving First Amendment rights of freedom of speech or assembly may not, regardless of its unpopularity with the professional group, be considered grounds for disciplinary action.

For example, some years ago medical societies attempted to exclude physicians associated with prepaid group practice clinics; courts found such attempts to deny the physicians their Constitutional rights. Criticism of the profession's current stand on governmental payment of medical bills (as opposed to unjustified public criticism of another physician's professional skills, for example) would undoubtedly not support any disciplinary action. Peaceful protests in civil rights, anti-war or other political contexts would also not support any attempt to revoke a physician's license or exclude or expel him from a medical society, no matter how infuriated all the other members might be.

"Gross immorality" in one's personal life may also be a justifiable ground for disciplinary action but the difficulty is to define the term. Most recent cases brought on this ground have involved physicians who were alcoholics or narcotics addicts. If such dependency on alcohol or drugs can be proved to have affected patient care or even that the physician was under the influence at the time he saw patients even though no harm was done, charges are usually brought as "unprofessional conduct" whereas if the drinking or drug abuse occurs at other times it is usually considered "gross immorality." While several cases in earlier years involved physicians who were sexually promiscuous with women who were not patients (in one of which apparently the women were other physicians' wives) and courts found that the affairs constituted "gross immorality" it is highly improbable that in the 1970's having a sexual liaison would, except in incredibly flagrant and bizarre circumstances be considered sufficiently immoral to justify disciplinary action even if the spouse obtained a divorce for adultery.

Thus the courts review actions of professional bodies in exclusion or discipline cases in the light of reasonableness and "fundamental fairness." Given the effects of a denial of a physician's application for membership in a medical society, is it fair to exclude him? Are the grounds for the expulsion of a member fair? Were the procedures followed at the disciplinary hearing fair and reasonable? If these questions are answered in the affirmative, courts are extremely reluctant to review actions of professional bodies on the grounds that the members' professional judgment should prevail.

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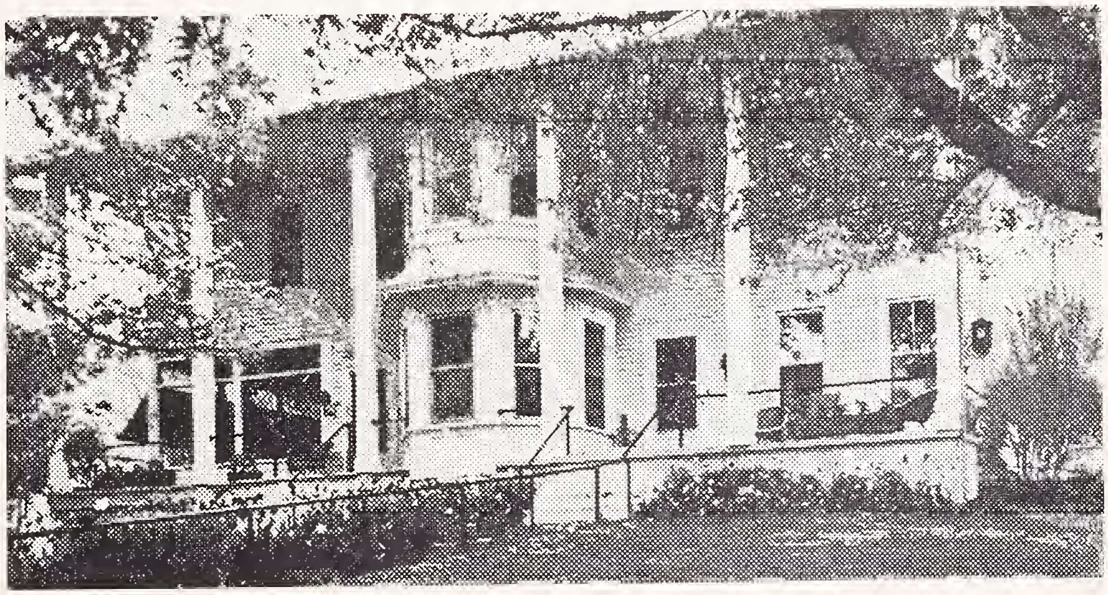

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Continuing Competence of Physicians: Progress Report

Report of the Board of Trustees of the AMA to the House of Delegates, Annual Meeting

At the 1970 Clinical Convention, the House of Delegates adopted Board of Trustees Report F, "Continuing Competence of Physicians," prepared by the Council on Health Manpower with assistance from the Council on Medical Education. This report examined the strengths and limitations of methods used by physicians to maintain and improve clinical competence, and discussed the incentives toward participation. The report emphasized the need to expand and improve the two major avenues to maintaining competence—continuing medical education and performance evaluation—and recommended the further development of intraprofessional incentives, including special awards or recognition, periodic specialty board recertification, and membership in the appropriate medical specialty and state medical society.

The three years since that report have seen an upsurge of interest and activities in continued physician competence by the AMA, medical educators, specialty boards, medical and medical specialty societies, hospital staffs, state licensing authorities and other professional groups. Most recently, Resolution 92 (A-73), introduced by the AMA Section on Internal Medicine, urged the use of performance evaluation, rather than continuing education or retesting, as an index of physician competence and a requirement for relicensure. Resolution 92 was referred to the Council on Health Manpower and the Council on Medical Education for study.

Board of Trustees Report Q, an interim report on Resolution 92 submitted at the 1973 Clinical Convention, noted the complexity of the issues involved, and indicated the need to involve the Council on Medical Service in reevaluation of policy.

The purpose of the present progress report, prepared jointly by the Board of Trustees' Council on Health Manpower, the Council on Medical Education and the Council on Medical Service in response to Resolution 92, is twofold:

(1) To summarize briefly the progress made in expanding and improving current methods of maintaining competence since the 1970 Report, and the growth of incentives toward such competence;

(2) To make preliminary recommendations as to those areas in which further effort seems most appropriate and needed.

A further report on this subject, with recommendations for long-range activity, will be submitted by the three Councils at the 1974 Clinical Convention.

Continuing Medical Education Programs

As pointed out in the 1970 Report, the number of continuing medical education courses for physicians offered by medical schools, hospitals, medical and medical specialty societies, voluntary health organizations and similar groups increased by about 10% annually over the nine-year period 1961-62 to 1970-71—from 1,105 to 2,319. The Council on Medical Education, with its Advisory Committee on Continuing Medical Education, is responsible for the review, analysis, and accreditation of institutions offering these programs. A yearly Council report, titled "Continuing Education Courses for Physicians," lists most continuing education programs by location and sponsorship, specialty area, enrollments, and other factors.

The Council on Medical Education has since 1964 conducted an accreditation program for institutions and organizations sponsoring continuing education courses. In addition, that Council has encouraged state medical associations to establish similar accreditation for continuing medical education programs originating in community hospitals, county medical societies and other locally oriented medical organizations. Currently, 18 state medical associations have been approved by the Council to accredit institutions sponsoring such intrastate continuing education activities. The number of institutions accredited through both national and state mechanisms has increased from 86 in 1970 to 290 in 1974.

Beginning with the 1972 issue, the Council's annual report on "Continuing Education Courses for Physicians" listed only courses sponsored by accredited institutions or organizations; nonetheless, the total number of courses reported for 1973-74 increased to 2,441. Physician registration in such courses has also shown substantial annual growth, exceeding 300,000 last year. This progress was summarized in a Council report, "A Policy Statement on Continuing Medical Education," adopted by the House of Delegates at the 1973 Annual Convention. The report reaffirmed AMA's commitment to continuing medical education, self-assessment programs and the Physician's Recognition Award.

The 1970 Report on "Continuing Competence of Physicians" emphasized the need to align format, training and content of continuing education programs as closely as possible to the actual needs of current medical practice, if such programs were to significantly influence levels of clinical competence. Evidence that this need has been recognized is seen in the marked increase in physician self-assessment programs and their use to modify continuing education experience. In 1970, five medical specialty societies reported self-assessment programs in operation. By 1972, 13 specialty societies were conducting such programs and of these, 11 specialty societies reported 89,000 registrations for self-assessment examination. The most recent AMA survey shown 20 specialty societies and 2 other medical organizations with operational, or near operational, self-assessment programs. This form of self-evaluation enables the physician to pinpoint his own educational needs and indicates to those planning continuing education which areas of knowledge require emphasis.

Increased study is now being devoted to utilizing the findings of peer review programs of all types as similar content modifiers for continuing education. Under consideration at AMA is an expanded data system which would automatically record physician participation in continuing education. Further development of this system might permit incorporation of educational needs identified through peer review programs into medical education activities. This would allow the physician to refine his personal program of continuing medical education. Efforts in this direction should be continued and expanded.

Performance Evaluation

As noted in the 1970 Report, medical care evaluation, or the review of performance by professional peers, is probably unsurpassed as a potential method for improving clinical competence. Peer review, encompassing both retrospective medical audit and concurrent review programs within and outside the institution, not only helps to "target" continuing medical education needs, but constitutes an immensely valuable continuing education technique in itself. These activities, too, have shown steady growth over the past few years.

Standards of the Joint Commission on Accreditation of Hospitals continue to stress the importance of an organized medical care evaluation program conducted by each hospital medical staff, utilizing objective criteria for appropriate care, and providing for suitable action to correct deficiencies, whether through practitioner education and counselling, or other more stringent measures. JCAH standards require the medical staff to provide a continuing program of professional education or give evidence of participation in such a program, and encourage use of medical care evaluation findings in planning such education.

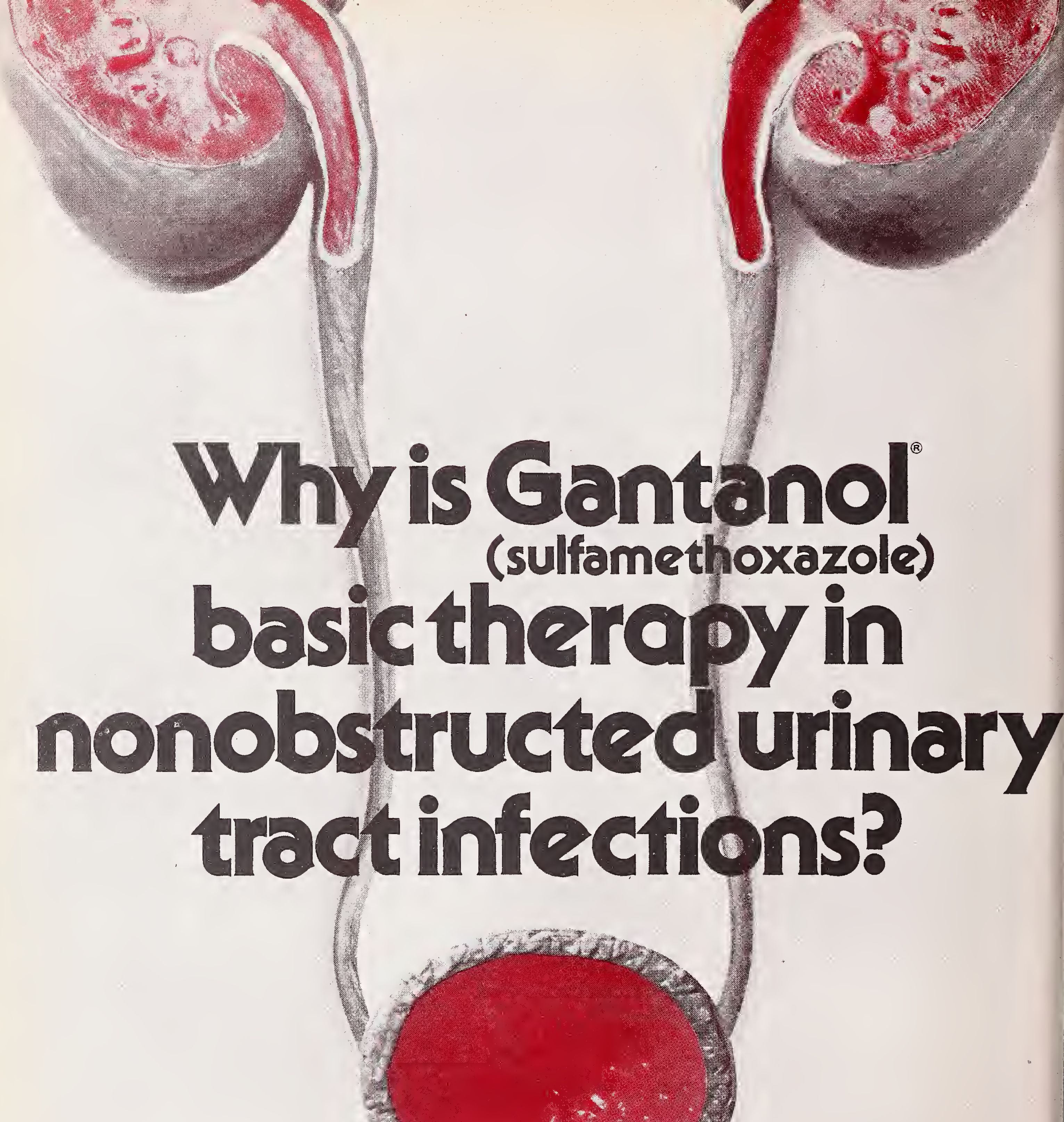
Formal out-of-hospital peer review programs have also increased substantially. A 1972 survey of state and county medical society peer review activities by the AMA Council on Medical Service (CMS Report F, A-72) showed that 45 of the 50 state associations responding had a formal review mechanism in operation, and that 33 of these had been established since 1960. Of the 142 county societies operating formal review committees, 128 were established since 1954. The survey noted that a significant recent development in peer review is the increase in state medical association involvement, primarily an assumption of responsibility to assure that peer review is being done. State associations are not necessarily performing review at the state level, although some already are doing it and others are prepared to do so, especially where the population is sparse or where local review activities have not been established. The role of other state associations is rather that of aiding and assisting the local societies to get their own programs activated and functioning effectively.

Interest in and commitment to professional review has been intensified by current discussion of PSRO legislation. It is not within the purview of this report to discuss that particular legislative program. Regardless of PSRO's ultimate disposition, however, it is likely that organized review of physician performance under direction of the profession will continue to expand. At the 1973 Clinical Convention, the House reaffirmed its commitment to the principle of peer review under professional direction.

The prospects are good for more comprehensive and extensive information on physician performance in care of patients. However, more work is needed. As pointed out in the 1972 Council on Medical Service report:

> "Professional review committees are active and well organized in many localities, and the dimensions of a comprehensive peer review program are being explored in varying degrees, with much of the accomplishment dependent upon the organization and techniques available. It is equally apparent from the responses to the survey, however, that in too many areas review efforts are nonexistent or are fragmented, with necessary coordination yet to be accomplished. The lack of a consistent pattern of operating relationships between medical staff utilization review programs illustrates emphatically one essential area for closer coordination."

In addition, the process of performance evaluation itself required further refinement. Technically speaking, methods do not yet exist for making reliable and valid direct measurements of physician performance. "Physician performance" is often equated with "quality of care," however, there is



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pura, hypoprothrombinemia and methemoglobinemia); *allergic reactions* (erythema multiforme, skin eruptions, epidermal necrolysis, urticaria, serum sickness, pruritus, exfoliative dermatitis, anaphylactoid reactions, periorbital edema, conjunctival and scleral injection, photosensitization, arthralgia and allergic myocarditis); *gastrointestinal reactions* (nausea, emesis, abdominal pains, hepatitis, diarrhea, anorexia, pancreatitis and stomatitis); *CNS reactions* (headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo and insomnia); *miscellaneous reactions* (drug fever, chills, toxic nephrosis with oliguria and anuria, periarteritis nodosa and L.E. phenomenon). Due to certain chemical similarities with some goitrogens, diuretics (acetazolamide, thiazides) and oral hypoglycemic agents, sulfonamides have caused rare instances of goiter production, diuresis and hypoglycemia as well as thyroid malignancies in rats following long-term administration. Cross-sensitivity with these agents may exist.

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as yet no operational definition of "quality." While current performance evaluation efforts can reliably and clearly describe physician actions and compare them with professionally determined criteria, evidence that "appropriate" physician behaviors are correlated with favorable patient outcomes is incomplete. Further study of their relationship is a recognized research priority and should be pursued by the AMA Center for Health Services Research and Development and other appropriate groups.

Incentives for Maintaining Competence

The 1970 Report on Continuing Competence of Physicians identified three general categories of incentives for maintaining competence: (1) the granting of awards or similar recognition, (2) the use of intraprofessional requirements for retention of membership privileges or professional certification, and (3) the modification of licensing or relicensing practices. All three have received emphasis in the three years since.

The AMA Physician's Recognition Award, established in 1969, is granted to any physician who participates in at least 150 hours of continuing medical education of a specified nature over a three-year period. This award is in its second three-year cycle, and over 46,000 physicians have qualified and/or requalified for it as of January, 1974. In addition to the national program, four state medical associations—Arizona, California, Oregon and Pennsylvania—and one specialty—the American Academy of Family Physicians—now record physician participation in continuing medical education. Any physician qualifying under these programs also qualifies for the AMA Award.

In 1970, one state medical association—Oregon—required participation in continuing education as a condition for membership; currently seven state associations have such requirements and 13 others have adopted recommendations for voluntary participation in continuing education by all members. The American Academy of Family Physicians also requires continuing medical education as a condition for membership, and the American Society of Anesthesiologists has established "guidelines" for continuing medical education for its members.

The American Board of Family Practice requires recertification of its diplomates every six years. The recertification will likely be based on continuing education experience, a short cognitive examination on new medical information, and on evaluation of practice. More recently, the American Board of Internal Medicine has begun a voluntary recertification program for its diplomates at minimum intervals of six years after initial certification in the specialty, based on a recertification examination. Applicants for recertification will be required to register for the American College of Physicians' Medical Knowledge Self-Assessment Program (MKSAP III) prior to taking the Recertification Examination so as to update their knowledge and discover any gaps in their knowledge or experience. The recertification examination will be based largely on material in the MKSAP. Commenting on this recertification program in December, 1973 the American Society of Internal Medicine stated its belief that assessment by performance is the preferred, and the only meaningful approach to evaluating the abilities of the practicing internist, but acknowledged that while acceptable techniques are being developed for such evaluation, individual ASIM members might wish to avail themselves of other techniques: continuing medical education, self-assessment, and voluntary examination.

The ASIM expressed concern as to whether the results of any challenge examination can directly relate to a level of performance in practice, and asked whether such an examination, based on recall of knowledge across the diverse subspecialty areas of internal medicine, could capture the relevant dimensions of the clinical competence of the individual internist as he engages in his actual practice activities within his self-defined boundaries. These concerns regarding the validity of challenge examinations are also highly pertinent to the questions of relicensure, and they merit thoughtful study.

At its annual meeting in March, 1973, membership of the American Board of Medical Specialties approved the following recommendations concerning recertification:

> "That the American Board of Medical Specialties adopt in principle, and urge concurrence of its member boards with the policy that voluntary, periodic recertification of medical specialists become an integral part of all national medical specialty certification programs, and further that ABMS establish a reasonable deadline when voluntary periodic recertification of medical specialists will have become a standard policy of all member boards."

The ABMS has not, as yet, established such a deadline, however.

In the area of licensing, the controversial report of the Committee on Goals and Priorities of the National Board of Medical Examiners has proposed postponing the licensure of physicians for independent practice until completion of specialty training and receipt of specialty certification. The NBME GAP Committee proposes a single qualifying examination upon graduation from medical school which, together with the medical school's evaluation, would enable state medical licensing boards to grant the graduate M.D. a permit to practice medicine under supervision during graduate education. A full license for independent practice could then be awarded by a state board following completion of graduate medical education and the awarding of specialty board certification, presumably without requiring a separate licensing examination. For those who are not certified by a specialty board, alternate prerequisites for licensure would be determined by the state boards.

Following completion of graduate education and entry into independent practice, periodic evaluation of professional competence leading to recertification and perhaps relicensure based on such recertification is envisioned throughout the professional career of the physician. The responsibility for recertification will rest, the GAP Committee believes, with the agencies that grant specialty certification in the first instance, the specialty boards.

This proposal raises several basic questions. For example, if licensure is to be awarded automatically on demonstration of knowledge in a limited area of medicine, should that license authorize practice only within that specialized area as well? What effects would such a policy have on the availability of health services? In addition, if relicensure is to be based on specialty board recertification, the concerns with recertification referred to earlier in this report need further study.

Finally, three states—Kansas, Maryland and New Mexico—have enacted legislation enabling the state board of medical examiners to require evidence of participation in continuing education as a condition for re-registration of the physician's license. In Maryland and New Mexico, the state boards have implemented this legislation through regulations requiring, respectively, 150 and 120 hours of acceptable continuing medical education every three years as a condition for continued licensure. This legislation in Kansas has not been implemented. It is significant that the Boards of Medical Examiners in New Mexico and Maryland accept the AMA Physician Recognition Award as meeting their continuing medical education requirement for re-registration of the license to practice.

In discussing periodic relicensure, the 1970 Report on "Continuing Competence of Physicians" noted that there was insufficient documentation of the degree to which either participation in continuing education or successful test performance was predictive of improved clinical ability. For this reason, the report questioned whether incorporating such requirements into licensing laws would result in any significant improvement in competence, particularly since such requirements would have to be set at minimal levels. This question still remains pertinent today.

In a somewhat similar vein, Resolution 92 questions the validity of participation in continuing medical education as an index of improved clinical competence, and urges instead the use of performance evaluation. As pointed out earlier in this report, however, the Council on Health Manpower, Council on Medical Education and Council on Medical Service believe that both performance evaluation and continuing medical education should be further improved, that the usefulness of challenge examinations should be further evaluated, and that the relationships of all three to improved care should be documented or refuted before any is proposed as a valid criterion for relicensure. The Councils further believe that performance evaluation and continuing education are not mutually exclusive approaches but rather complementary facets of the same process of striving for professional excellence.

Based on the above consideration, the three Councils, in collaboration with medical educators, medical and medical specialty societies, licensing authorities and specialty boards, will give special study to the following in preparing a further report on the issues raised by Resolution 92 (A-73):

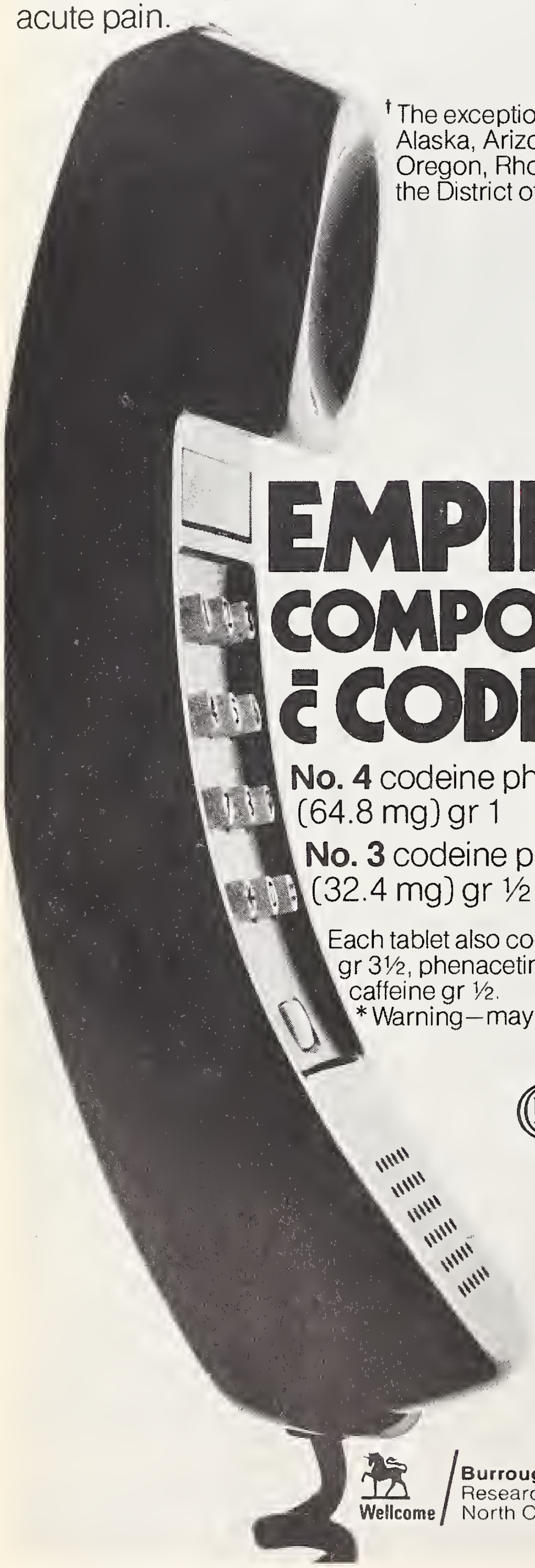
(1) the methods by which continuing medical education, self assessment and performance evaluation might be utilized together—each enhancing the other—in an integrated program to improve physician competence;

(2) the degree to which continuing medical education experience, participation in performance evaluation, and scores on challenge examinations are individually correlated with improved quality of care as evidenced by patient outcomes, and the consequent validity of such requirements as criteria for relicensure; and

(3) the validity and acceptability of the proposals advanced by the Committee on Goals and Priorities of the National Board of Medical Examiners and others concerning licensure, including the desirability of the basic changes which would be needed in the nature of medical licensing.

In the interim, the Councils on Health Manpower, Medical Education and Medical Service and the Board of Trustees recommend:

(1) that continued strong encouragement be given to current efforts to improve both the process and the extent of performance evaluation



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and peer review programs under professional direction and control;

(2) that previous AMA policy encouraging physicians' participation in continuing medical education, self assessment, and qualification for the Physician's Recognition Award be strongly reaffirmed;

(3) that continued study of the advisability of periodic recertification programs by medical specialty boards be encouraged; and

(4) that pending the outcome of the above-mentioned considerations, states be urged to delay implementation of existing relicensure laws or to withhold enactment of such legislation at this time.

Medicine in China

Continued from Page 165

comings in respect to the amenities of the hospitalization, but the outcome would probably be equal in quality to that obtainable almost anywhere in the Western World.

In any event, it is hard to see how one could improve greatly on the current utilization of available resources in Chinese medicine. It is no doubt good that communications have been reestablished. The Chinese clearly have much to contribute from their skills, inventiveness, and sheer mass of clinical material. In turn we may aid them in successful avoidance of doctrinaire substitutes for scientific medical care in the years to come.

GIRLS' SMOKING MATCHES BOYS'

Surveys of cigarette smoking among teenagers have revealed that there is no longer any appreciable difference in the smoking habits between boys and girls, although 6 years ago only half as many girls as boys smoked.

A report issued by the National Clearinghouse for Smoking and Health, a unit of the U.S. Public Health Service's Center for Disease Control, showed that in 1968 the number of girls from 12 through 18 years of age who smoked was 8.4%, compared to 14.7% of boys. By 1974 the figure for girls had risen to 15.3%; boys stood at 15.8%.

"During the 6 years covered by the surveys, the proportion of boys who smoke at lease once a week changed very little," the report stated. "Among girls, however, there has been a gradual increase in the proportion of smokers in every age group. This has practically eliminated the difference in smoking behavior of the two groups."

Out of the Licensure Jungle at Last?

Robert C. Derbyshire, M.D.

Medical licensure remains something of a jungle, despite the best efforts of many individuals to clear out the undergrowth and lay down orderly paths. The latest effort is that of the Committee on Goals and Priorities of the National Board of Medical Examiners.[1] I applaud the effort, but I doubt that it can succeed in the foreseeable future.

In summary, the committee proposes abandonment of the present multiple system of examination for licensure and certification in favor of a three part progression: an examination called Qualifying A, which would show whether the medical school graduate could perform patient care under supervision; Qualifying B, which would certify that the graduate of a residency was qualified for independent specialty practice; and eventually Qualifying C to examine the physician's continued competence at intervals throughout his professional career. This radical proposal impinges on the interests of state boards of medical examiners, state legislatures, hospitals, medical schools, and specialty boards and will, I predict, meet resistance from all of them.

The National Board of Medical Examiners has consistently tried to maintain uniformly high standards and to help untangle the perpetual snarl of the non-system that is medical licensure, although its certificate has never gained complete and unqualified acceptance by all the state licensing boards. The quality of its examinations has long been recognized by educators and practicing physicians alike as surpassing that of the majority of the state examinations; the refusal of some state boards to endorse its certificate is based upon the capriciousness of politics and upon extreme parochialism.

The National Board has grown steadily both in stature and in the scope of its operations. Beginning in 1952, under the able direction of Dr. John P. Hubbard, the board, by developing and promoting objective methods of examination, has become a model in the emerging field of precise evaluation of medical knowledge.

This exponential growth in its activities was one reason why the board felt impelled to assess its mission both for the present and for the future. So in 1971 it established the Committee on Goals and Priorities to look ahead to the next 10 years. Under the chairmanship of Dr. William D. Mayer, the committee contained broad representation from the fields of both undergraduate and graduate medical education. An unfortunate omission, however, was any representation from the area perhaps most deeply concerned, that of medical licensure.

Now, two years later, the committee has published its report entitled "Evaluation in the Continuum of Medical Education." It is a thoughtful appraisal of the past, present, and future of medical education and accreditation. As noted above, it proposes radical changes in the entire process of evaluation.

A principal concern of the committee was the fragmentation of medical education—underscored a few years ago by Millis[2] and Coggeshall[3]—among the essentially independent experiences of medical schools, internship, and residency. Although the acquisition of the M D is only the halfway point in the education of most physicians, and although the internship is generally recognized as inadequate preparation for the independent practice of medicine, every state now grants an unlimited license either upon graduation from medical school or upon completion of only one additional year of training.

As a first step in creating a continuum instead of what it calls the present trichotomy, the committee report recommends the Qualifying A examination, whereby on graduation from medical school and before entering graduate education the individual would be required to demonstrate his competence to assume responsibility for the care of patients in an institutional setting under supervision. This examination would be designed to "measure knowledge, skills, and attitudes that are predictive of acceptable performance at the next level of responsibility."

If successful completion of this examination became a legal requirement in all states, with the state boards issuing permits, it would provide an assurance of at least minimal competence of house officers that is now lacking.

As far as the content of the examination is concerned, the report states, "The scope, content and design of Qualifying A should reflect trends in medical education and the change in purpose of the evaluation process at this level (i.e., from qualification for independent practice to qualification for patient care in a supervised setting).

DR. ROBERT C. DERBYSHIRE, Secretary-Treasurer, New Mexico Board of Medical Examiners. Past President, Federation of State Medical Boards of the United States.

Abridgement of an article originally published in *Hospital Practice* January, 1974. Printed by permission of the Editor.

Reprint requests to 227 E. Palace Avenue, Santa Fe, New Mexico 87501 (Dr. Derbyshire).

"This assessment should place emphasis on the ability to integrate and apply basic science knowledge in solving problems related to patient care. The examination should include components of basic science disciplines necessary to most career choices so that basic science information is assessed within the broad spectrum of clinical careers. Moreover, since undergraduates will aim toward specific clinical careers, in-depth comprehension of clinical skills need not be tested. However, those basic aspects of clinical medicine that are required for all specialties should be examined."

The concept of Qualifying A is therefore essentially a combination of Parts I and II of the present National Board examination. Its design as a multidisciplinary test should alarm no one, not even the state licensing authorities, who are surely aware that the National Board has already adopted a flexible cross-disciplinary approach to conform to current trends in undergraduate curricula.

But it will presumably not satisfy the basic scientists in the medical schools and on the National Board test committees who already feel that the pure basic sciences are being pushed out of the curriculum and examinations and that the result in the long run is going to be poorer doctors.

I must agree that if basic science is brought in only as it applies to a clinical situation, we might be getting perilously close to a trade-school concept. There could be a danger that people taught and examined in this way would not have the background to grasp new basic science concepts as they come along, and then to apply these in treating patients.

At present I am unable to assess the possible attitudes of the medical schools towards the proposal to re-vamp the National Board examinations. Possibly they would be little affected as, no doubt, internal assessment examinations would still be available to them from the board. Whether any of them would make the awarding of the M.D. degree contingent upon the successful completion of Qualifying A, I should not venture to guess.

The concept of Qualifying A assumes that all students would enter graduate medical education after receiving the M D degree. (A study of the 1960 and 1964 classes showed that 89% did so.)[4] Therefore, the examination would be required for all, including foreign medical graduates. This would eliminate the current double standard under which the great majority of Americans qualify for licensure by passing the National Boards, while foreign graduates usually must pass the ECFMG for appointment to a house staff and, later, FLEX for licensure. Qualifying A and B would replace all these exams.

No doubt those elite hospitals whose house staff positions are eagerly sought after by medical graduates would not oppose the imposition of Qualifying A as a requirement for appointment. They are already obtaining the cream of the crop of American graduates, and they might welcome an examination if it would further help them in their selection procedures.

But what about the lesser-known hospitals, accredited for graduate education but not widely acclaimed as seats of learning? The requirement of successful completion of Qualifying A would surely compound their difficulties. This might not be entirely bad if it resulted in the discontinuance of some programs that really do not merit approval.

There is a further complication, however: the candidates who failed Qualifying A. Would they be barred from graduate education and thus denied the chance eventually to become licensed? Recognizing the possibility that some candidates would fail, the Committee acknowledges that the state boards at their discretion might still permit these students to care for patients under supervision. It urges, however, that there be a provision that the candidate must pass the examination within a year and that the educational authorities concerned guide him during this period. In other words, he would be accepted as a house officer on a probationary basis.

This would set up another double standard, of qualified and probationary house officers. Those on probation and needing the most supervision would go into the marginal training programs least equipped to prepare them to pass Qualifying B. The failure rate today of foreign graduates in specialty board examinations may be three or four times that of Americans by reason of the poor training they receive in service residencies.

Hospital boards of directors, administrators, and their corporate attorneys would no doubt become acutely aware of the medico-legal implications of the presence of probationary house officers. The 1965 Darling[5] case in Illinois resulted in a jolting decision that stated, in essence, that the hospital is responsible for the quality of practice of its staff members. In the light of this decision, hospital authorities ought to be extremely reluctant to employ a physician who had failed to pass Qualifying A. Regardless of how carefully he was supervised, there would always be the chance that an accident would occur. One can easily picture the glee of a plaintiff's attorney in a malpractice action who discovered that the involved doctor was not legally qualified. If all hospitals refused to accept the risk, this would indeed be a late date to exclude graduates who were unsuited to medicine.

Despite the reservations I have expressed, I find Qualifying A much more acceptable than Qualifying B. This second external assessment would consist of an examination in a recognized specialty, including family practice. The examination would be given in association with participating specialty boards, which would be responsible for setting standards. The committee report states, "These examinations should be designed to measure those characteristics (Knowledge, skills, and attitudes) that are predictive of acceptable performance for independent medical specialty practice, and should provide the basis for full legal licensure."

As a concession to states' rights, the report states that such certification "should be requisite for, but not a guarantee of licensure. Licensure to practice medicine will continue to be the responsibility of licensing authorities of the states and territories."

Granted that the present practice of granting unrestricted licenses to physicians to practice medicine and surgery in all their branches borders on obsolescence. There are many practical reasons for the refusal of states to license specialists. As far as the protection of the public is concerned, hospital rules and the threat of malpractice actions in large measure suffice to prevent the invasion of specialized fields by unqualified individuals.

Historically the members of the Federation of State Medical Boards of the United States have been united only in their adherence to States' rights. But in 1968, with the inauguration of FLEX, the Federation took its most significant step since its founding in 1913. The examination is now given by 49 state Boards, but it has only partly untangled the jungle of medical licensure. With 16 states clinging to their anachronistic basic science laws, with the imposition of additional requirements by some states and the manipulation of FLEX scores by others for political reasons, the goal of uniform standards is not yet in sight.

Still, in the light of the past inability of Federation members to agree on much of anything, their acceptance of FLEX has been phenomenal. Will they consent to abandon it after only five years in favor of Qualifying A and B, which are completely untried? I do not foresee any immediate move of the Federation to do away with FLEX or even to phase it out.

The abandonment of FLEX and, by implication, the ECFMG requirement, would present serious legislative problems. Amending the medical practice laws to regulate the entry of medical school graduates into graduate education and to permit licensure by specialty would be a revolutionary step. Boards of Medical Examiners are slow to accept even minor changes, often slow to the point of exasperation. There are reasons for this, however, one of the most important being their distrust of the legislators.

No matter how lofty the motives of the boards in requesting amendments, the lawmakers almost invariably begin to make mischief by proposing additional amendments of their own that would often harm the public. Moreover, their motives are usually based upon parochialism or caprice. Under the best of circumstances, the physician who promotes an amendment is subjected to an inquisition by legislative committee members who, without any prior study, proceed to attempt to tear the existing law to pieces. As one who has been on the firing line for many years, I never cease to be appalled at the struggles the medical profession must engage in to promote the passage of bills that are obviously in the public interest—and to prevent harmful legislation.

Throughout the country, legislators are acutely aware of the so-called medical manpower shortage. They are tireless in their efforts to undermine standards in order to provide their constituents with medical care, regardless of its quality. An example is the repeal of the New Jersey law requiring that foreign house officers have ECFMG certificates.

In such an atmosphere, one cannot imagine representatives of medical societies and boards of medical examiners of 50 states proposing to their legislators that they pass laws forbidding doctors to begin practice immediately upon completion of an internship. Add to this the requirement that the time needed for full licensure be doubled, and the advocates of such bills would be laughed out of the legislative halls. From the practical standpoint, specialty licensure is an idea whose time has not yet come.

Though the Committee on Goals and Priorities declares that the province of licensure would remain with the states, many strong defenders of states' rights will be sure that the National Board is trying to usurp their prerogatives. Many will be certain that this is the road to national licensure, the mere thought of which fills them with horror. Infinite persuasion would be required to allay their suspicions.

The specialty boards particularly will be concerned about Qualifying B. A real fact of life is the high failure rate of candidates for specialty certification. A recent report of the American Board of Medical Specialties revealed failure rates on the written examinations ranging from 5% to 40%. Six boards had rates of over 20%.

By contrast, the failure rate on Part III of the National Boards has long averaged about 2%. Would the specialty boards be willing to lower their standards to approximate this figure? Already members of some specialty boards have declared privately that they will not. The young physician who faced at least three years of training after graduation from medical school would carry an intolerable burden if he knew that his chances of failing to obtain licensure might be 20% or more.

The committee has foreseen that some physicians would choose not to take Qualifying B and that others would fail. It recommends that such physicians be required to practice in an institutional setting until full licensure is achieved. It also points out that the state medical board at its discretion might issue them full licenses. It urges, however, that the board "require successful completion of the Qualifying A examination plus a minimum of two years of graduate education in an accredited program (and) full assurance from the graduate educational institution that the physician's performance during graduate education qualifies him for independent practice."

If his performance qualified him to practice a specialty, why would he be unable to pass the examination? Could we expect a program director, under pressure to fill his residency positions, to confess that after two or three years of his tutelage his residents who did not pass the examination were not qualified to practice? And would not politicians exert pressure on the state boards to license physicians who had failed by a few, or even many, points?

As in the case of Qualifying A, I believe medicolegal difficulties would be created not only for the physician who failed Qualifying B, and obtained a license anyhow, but for the program director who attested to his competence to practice. And let us suppose that someone who passed Qualifying B and was licensed as a general surgeon found it necessary to care for a patient with a heart attack, and the patient died. He could be even more vulnerable legally than at present, for practicing outside the scope of his license. I am not arguing that surgeons should treat heart attacks except in a dire emergency, or any other conditions outside their field. But it is difficult for almost any physician to stay strictly within the boundaries of his specialty, or even sometimes to know precisely what those boundaries are. Specialty licensure and the fear of professional liability suits could have him swelling the patient's bill by calling in consultants for any conditions that might conceivably be considered outside his own field. In its present form the proposal for Qualifying B seems completely unworkable.

The goals and priorities committee also briefly refers to a possible Qualifying C examination for the continuing evaluation of professional competence, possibly for relicensure. It outlines no definite plans aside from recommending that the National Board "be prepared to provide assistance to those agencies responsible for recertification in the event that episodic qualifying examinations become a part of the process (and) participate in developing assessment techniques."

I am pleased that the committee also recommends establishment of a National Board Council for Research and Development. Its work could be of paramount importance in improving methods not only for testing medical competence but for evaluating attitudes, moral qualifications, and personality so as to try to predict who will be a good doctor.

Possibly I have thought of too many potential complications arising from the committee's recommendations. In presenting these difficulties I have not intended to assume the role of wet blanket. I have merely tried to emphasize practical problems. The goals are admirable; the proposed methods of achieving them seem at present almost impossible to attain.

Dr. Hubbard[6] stated that the goals "can only be achieved if they are shared and supported by the many interdependent professional organizations that are equally concerned with assuring public accountability in health care and the education and evaluation of medical professionals." Much heated discussion of the proposals is already going on among members of interested groups. From the discussions may come a pathway out of the jungle of medical licensure. But it may have to be quite a different pathway from the one the Committee on Goals and Priorities has laid down.

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National Health Service Corps

Edward D. Martin, M.D.

P.L. 91-623, The Emergency Health Personnel Act of 1970, signed by the President in December 1970, led to the creation of the National Health Service Corps in the United States Public Health Service. The Corps represents a new endeavor by the Department of Health, Education, and Welfare in providing health care services.

The Corps places physicians, dentists, and other primary health care personnel in areas which have critical health manpower shortages. Unlike most arrangements for providing health care, it requires a *significant* involvement of the community in support of the practice. This helps the community to more nearly understand the problems which may confront the practitioner, both as an individual and as a professional, and frequently results in a happier relationship. It also reduces the load of non-professional activities (such as accounting and other administrative functions) which might be required of the physician.

The community is expected to provide whatever support it can, including office equipment, supplies, and practice management.

In this setting, the Corps physician functions as does any other practicing community physician. After consulting with other physicians, if any are practicing in the community, fees for service are determined. The program provides support in developing a well-functioning practice and helps the physician and family find their place in the community. The Corps has developed a problem-oriented medical record system and accounting and data system support for the physician which can be used with the local hospital, medical society, and the nearest medical center or school. The National Health Service Corps makes assignments where there is documented evidence of geographic and specialty maldistribution of medical care providers. It gives special attention to rural communities, for it is rural America that most dramatically shows the inadequacy of physicians and dentists. As more of these communities are identified—communities which have no physicians or a ratio of physicians to population worse than 1:4000—the Corps will accelerate its efforts to initiate a plan for health care for the rural population.

The Corps cannot solve this problem alone, but it is an important part of an overall health manpower strategy specifically designed to make steady progress toward adequate health care in underserved areas. As of June 30, 1974, there were 206 Corps sites staffed. A total of 323 communities are approved for the placement of health teams. Providing health care at the operable sites were physicians, dentists, nurses and other health professionals.

By July of 1975, the Corps is proposing to have 310 clinic sites in operation and a total of 430 areas approved for health teams. This will involve more than 800 health professionals, delivering needed health care in 46 states.

While placing health professionals in critical shortage areas is a major facet of the program, assisting these and other communities in developing the capacity to independently attract and retain health professionals is also a primary goal of the Corps.

In January 1972, the first group of health professionals, primarily physicians, dentists, and nurses, were placed in a dozen communities. Of the 89 clinic sites that have been providing services since June 1972, approximately 25 percent have become independent and no longer receive direct Federal support. An additional 21 communities, working in conjunction with the Corps, have developed a practice setting attractive enough to enable these communities to recruit their own physician.

Prior to June 30, 1974, 189 clinic sites were in operation. Of these 48 are now fully self-sustaining and repay to the U.S. Treasury all costs of the assignee's salary, fringe benefits and moving expenses.

Within the next year, the Corps expects more clinics to become independent. This is largely due to improved management techniques at the sites, more careful matching of assignees with the communities and an increased emphasis on recruitment of board eligible physicians who will not need to leave a community to get full professional training. Prior to the placement of a Corps Health team, the local governing body, professional societies (medical and dental) and the local planning agency are asked to document the need for assistance.

The documentation by the local medical society represents only an initial effort. The county medical society's input in the developmental aspects of its health needs are critical to the community's request for assistance. The society can provide advice on numbers and types of health professionals needed in the area; equipment required for establishing an active primary care practice; identify health resources locally as well as backup resources needed

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DR. EDWARD D. MARTIN, Associate Bureau Director, Office for National Health Service Corps., Bureau of Community Health Services, Health Services Administration, Department of Health, Education and Welfare, Rockville, Maryland.

for tertiary care; facilitate the integration of its physician and his wife into the medical community; assist in obtaining hospital staff privileges; facilitate a mechanism for rotational coverage in the evenings and weekends for the area. The acceptance of the Corps physician by his peers is another factor which will influence his remaining in the community.

In summary, the Corps is in no way the answer to this nation's health manpower dilemma, and it was never intended to be. However, the program has proven itself an important service initiative, which can strengthen the delivery of health care to hundreds of thousands of Americans in areas with critical health manpower shortages. A measure of success can be noted in the fact that the percentage of assignees who decided to remain in the Corps rose from 3 percent in 1973 after their first service period to 20 percent in 1974. This trend should continue to rise with better matching of assignees with communities, increased recruitment of board eligible physicians, and more active recruitment of physicians seeking a change from their present practices.

DEMOCRATIC PLATFORM SPEAKS TO HEALTH ISSUES

"We pledge that the new Democratic administration will lead in preventive health and comprehensive health efforts. Quality health care at least cost is a right of Connecticut citizens.

"The Commission on Hospitals must be directed and supervised by a qualified person who meets the statutory requirement, i.e., he shall be experienced in hospital administration.

"Effective regional health planning and service . . . will receive strong support . . .

"Encouragement will be given to new corporations . . . of area hospitals to plan cooperatively for the most effective, least costly, least duplicative, delivery of hospital care . . . Improved access to primary health care is urgently needed . . . Emergency rooms should not have to bear the burden of non-emergency medical services.

"We support the use of state funds for more family practice physicians, continued training of highly specialized physicians and programs . . . We strongly support a program of community medicine for those who are in serious need of care. We endorse sound training of para-professionals at the state education centers, and an effective licensing system. We urge greater recognition and utilization of the trained resources available in the nursing profession. We support effective implementation of the Emergency Medical Act."

(Preventive Care) "State funding must be earmarked for support of health districts now understaffed. Detection screening clinics, immunization, investigation, and sanitation services are woefully lacking . . . We support incentives to bring all of the towns into health districts. Large city health departments should be compensated for providing TB, VD, immunization and other services . . .

"We pledge continued support of research in and treatment of cystic fibrosis, sickle-cell anemia, Cooley's anemia, Tay-Sachs and other genetically-caused diseases.

"We support the serious in-depth investigation of the most effective alternatives to the traditional and highly expensive utilization of the hospital unit for medical care."

(Mental Health) "We support the establishment of necessary community based services . . . including preventative and rehabilitative services . . .

"We support coordination of the work of state hospitals with community programs.

"We are pledged to funding of grants to mental health clinics on a more reliable basis. We urge . . . a thorough review of the statutes relating to the rights and responsibilities of persons 16 to 18 years of age. . . . We support evaluation of local special education programs for handicapped children, including emotionally handicapped . . . while recommending state funding . . . be increased and prepaid to the towns.

"We urge that all necessary steps be taken to ensure the civil and legal rights of persons who have recovered from mental disorder . . .

"Continued support of regionalization of mental retardation services is endorsed. Staff and modern facilities (in state institutions) will have genuine support. We support well staffed group homes for the mentally retarded."

(Rehabilitation) "We pledge continued support of modern educational, vocational, and social rehabilitation services for the disabled, with special emphasis on job training . . . "

(Alcoholism) "Education on the nature of alcoholism to fully implement legislative intent to remove alcoholism as a crime from the statute books. We pledge an expansion of community treatment and rehabilitation services to deal with alcoholism as a sickness."

(Prevention) "We support genetic counseling availability . . . programs mandating measles and rubella immunization . . . screening for detection of lead poisoning . . . available for all children."

Editor's Note: *As is known, Connecticut voters elected Mrs. Ella Grasso, as Governor of Connecticut. The above platform is published as that of the incumbent party.*

FROM THE EXECUTIVE DIRECTOR'S OFFICE

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Assistant Executive Director
Public Affairs

William R. Richards, M.D.
Executive Director
Josephine P. Lindquist
Associate Executive Director

Leonard R. Tomat
Assistant Executive Director
Scientific Activities

CALL

ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1975 Annual Meeting of the House of Delegates is scheduled to be held in the Terrace Room of the Hartford Hilton Hotel, Hartford, on Wednesday, April 30. Commencing at 8:30 A.M. Following luncheon, the House will reconvene for the completion of its business.

James H. Root, Jr., President
Kenneth F. Brandon, Speaker of the House
Louis C. Backhus, Secretary

INTRODUCTION OF RESOLUTIONS

***Article V, Section 12, Par. 3 of the Bylaws of the Society provides that:**

All resolutions to be considered as regular business at any regular meeting of the House of Delegates must be in the hands of the Speaker not later than seventy-two hours before the opening of that meeting. All resolutions and recommendations published in the official agenda distributed to the members of the House prior to the meeting at which action is to be taken shall be considered as regular business. Resolutions presented later than seventy-two hours before the opening of a meeting will be referred for consideration as regular business by the House only when they are presented by the Council or accepted for consideration by majority vote of the delegates present. Any resolution which does not qualify in accordance with the aforesaid provisions for consideration as regular business may be accepted for action by a majority vote of the delegates present and, if so accepted, shall be referred at once by the Speaker to a reference committee. Any such reference committee shall consider resolutions referred to it and shall report, with recommendations to the House before adjournment of the meeting.

PROPOSED AMENDMENTS TO THE BYLAWS

The following proposed amendment to the Bylaws was presented to the House of Delegates on November 20, 1974 and was tabled for consideration and action at the next regular meeting of the House of Delegates.

In accordance with the Bylaws, this amendment will be published in Connecticut Medicine "on one or more occasions prior to the next meeting . . . at which meeting the amendment shall be taken off the table and acted upon by the House of Delegates."

SUBJECT:
PROPOSED AMENDMENT TO THE BYLAWS RE INTRODUCTION OF RESOLUTIONS, REPORTS, ETC.

Introduced by the Council

PURPOSE

To establish earlier deadlines for the submission of resolutions, reports and similar items of business to the House of Delegates. (Present Bylaw appears above.*)

AMENDMENT
ARTICLE V-HOUSE OF DELEGATES

Section 12. Procedure

Par. 3. RESOLUTIONS. Resolutions may be introduced by any Active or Life Member of The Society, in compliance with the following provisions.

a. All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that

Continued on page 194

New Haven County *Continued from page 7*

William B. Lyons, M.D., V.A. Hospital, West Haven, Conn. 06516

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Qaiyum Mujtaba, M.D., 310 Winthrop Avenue, New Haven, Conn. 06511

Iradj F. Nejad, M.D., 134 Grandview Avenue, Waterbury, Conn. 06708

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Villamor M. Parilla, M.D., 416 Highland Avenue, Cheshire, Conn. 06410

Kyle D. Pruett, M.D., 315 Whitney Avenue, New Haven, Conn. 06510

Aleflor T. Ragaza, M.D., 2044 Bridgeport Avenue, Milford, Conn. 06460

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Melvyn Ranish, M.D., 475 Chase Parkway, Waterbury, Conn. 06708

Erlinda Rauch, M.D., 416 Highland Avenue, Cheshire, Conn. 06410

Norman R. Richards, M.D., 335 Meriden Road, Waterbury, Conn. 06705

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Norman S. Rosenthal, M.D., Yale-New Haven Hospital, New Haven, Conn. 06504

Martin Rosman, M.D., 280 Broad Street, Milford, Conn. 06460

Dwight M. Rost, M.D., Waterbury Hospital, Waterbury, Conn. 06720

David Rothstein, M.D., 912A Heritage Village, Southbury, Conn. 06488

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Michael Stitelman, M.D., 129 Whitney Avenue, New Haven, Conn. 06510

Elsa L. Stone, M.D., 501 George Street, New Haven, Conn. 06511

Gordon Strothers, M.D., 98 York Street, New Haven, Conn. 06511

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Jose R. Villaluz, Jr., M.D., 54 Central Avenue, Waterbury, Conn. 06702

Maynard C. Wheeler, M.D., Union Square, Southbury, Conn. 06488

IMPORTANT INFORMATION: *This is a Schedule V substance by Federal law; diphenoxylate HCl is chemically related to meperidine. In case of overdosage or individual hypersensitivity, reactions similar to those after meperidine or morphine overdosage may occur; treatment is similar to that for meperidine or morphine intoxication (prolonged and careful monitoring). Respiratory depression may recur in spite of an initial response to Nalline® (nalorphine HCl) or may be evidenced as late as 30 hours after ingestion. LOMOTIL IS NOT AN INNOCUOUS DRUG AND DOSAGE RECOMMENDATIONS SHOULD BE STRICTLY ADHERED TO, ESPECIALLY IN CHILDREN. THIS MEDICATION SHOULD BE KEPT OUT OF REACH OF CHILDREN.*

Indications: Lomotil is effective as adjunctive therapy in the management of diarrhea.

Contraindications: In children less than 2 years, due to the decreased safety margin in younger age groups, and in patients who are jaundiced or hypersensitive to diphenoxylate HCl or atropine.

Warnings: Use with caution in young children, because of variable response, and with extreme caution in patients with cirrhosis and other advanced hepatic disease or abnormal liver function tests, because of possible hepatic coma. Diphenoxylate HCl may potentiate the action of barbiturates, tranquilizers and alcohol. In theory, the concurrent use with monoamine oxidase inhibitors could precipitate hypertensive crisis.

Usage in pregnancy: Weigh the potential benefits against possible risks before using during pregnancy, lactation or in women of childbearing age. Diphenoxylate HCl and atropine are secreted in the breast milk of nursing mothers.

Precautions: Addiction (dependency) to diphenoxylate HCl is theoretically possible at high dosage. Do not exceed recommended dosages. Administer with caution to patients receiving addicting drugs or known to be addiction prone or having a history of drug abuse. The subtherapeutic amount of atropine is added to discourage deliberate overdosage; strictly observe contraindications, warnings and precautions for atropine; use with caution in children since signs of atropinism may occur even with the recommended dosage.

Adverse reactions: Atropine effects include dryness of skin and mucous membranes, flushing and urinary retention. Other side effects with Lomotil include nausea, sedation, vomiting, swelling of the gums, abdominal discomfort, respiratory depression, numbness of the extremities, headache, dizziness, depression, malaise, drowsiness, coma, lethargy, anorexia, restlessness, euphoria, pruritus, angioneurotic edema, giant urticaria and paralytic ileus.

Dosage and administration: ***Lomotil is contraindicated in children less than 2 years old.*** Use only Lomotil liquid for children 2 to 12 years old. For ages 2 to 5 years, 4 ml. (2 mg.) t.i.d.; 5 to 8 years, 4 ml. (2 mg.) q.i.d.; 8 to 12 years, 4 ml. (2 mg.) 5 times daily; adults, two tablets (5 mg.) t.i.d. to two tablets (5 mg.) q.i.d. or two regular teaspoonfuls (10 ml., 5 mg.) q.i.d. Maintenance dosage may be as low as one fourth of the initial dosage. Make downward dosage adjustment as soon as initial symptoms are controlled.

Overdosage: Keep the medication out of the reach of children since accidental overdosage may cause severe, even fatal, respiratory depression. Signs of overdosage include flushing, lethargy or coma, hypotonic reflexes, nystagmus, pinpoint pupils, tachycardia and respiratory depression which may occur 12 to 30 hours after overdose. Evacuate stomach by lavage, establish a patent airway and, when necessary, assist respiration mechanically. Use a narcotic antagonist in severe respiratory depression. Observation should extend over at least 48 hours.

Dosage forms: *Tablets,* 2.5 mg. of diphenoxylate HCl with 0.025 mg. of atropine sulfate. *Liquid,* 2.5 mg. of diphenoxylate HCl and 0.025 mg. of atropine sulfate per 5 ml. A plastic dropper calibrated in increments of ½ ml. (total capacity, 2 ml.) accompanies each 2-oz. bottle of Lomotil liquid.

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Continued from page 191

meeting shall be considered as regular business of the House of Delegates.

b. Component county associations whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc., be considered regular business if they are received later than fifteen days prior to the date of the meeting.

c. Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.

d. Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provision of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.

Summary of Actions
Council Meeting

Wednesday, January 15, 1975

I. Attendance

Present in addition to the Chairman, Dr. D. A. Grendon, and the Vice Chairman, Dr. C. W. Johnson, were: Drs. Root, Jr., VanSyckle, Spitz, Backhus, Brandon, Nolan, Fabro, Bradley, Hess, Cramer, Rubinow, Ragland, Jr., James, Krinsky, Freedman, Roch, Kamens, McGarry, Canzonetti, Sadowski, Harkins, Magram, Eslami, Barrett and Klare.

Also present were: Mrs. Roch (Pres., Woman's Auxiliary), Mrs. Lindquist, Mr. Tomat, Mr. Sweeney, Mr. Sullivan (AMA), Mr. Olson (FCMA), Mr. Armato (FCMA), and Dr. Richards.

Absent were: Drs. Gardner, Granoff, Dambeck and Sonnen.

II. Routine Business

Approval of Minutes

As published and distributed, it was VOTED to approve the minutes of the meeting of December 19, 1974.

Life Memberships

It was VOTED to approve applications for Life Membership received from the following eligible Active Members:

Vincent P. Cenci, 854 Farmington Avenue, West Hartford.
Jean G. deChabert-Ostland, 60 Gillett Street, Hartford.
Rolf E. Katzenstein, Cheshire Street, Cheshire.
Frederick C. LaBrecque, 151 Grove Street, Waterbury.
John L. Meunier, 24 Church Street, Torrington.
William R. Richards, 160 St. Ronan Street, New Haven.
W. Leslie Smith, 85 Jefferson Street, Hartford.
Frederick A. Wies, 690 Howard Avenue, New Haven.

Date of Next Meeting

The next meeting of the Council will be held on Thursday, February 20, 1975.

III. Old, New and Special Business

Election of Student Members

It was VOTED to elect to Student Membership the following two Connecticut residents who are enrolled in U.S. medical schools:

Nicholas S. Ranno, 98 Camp Street, Middletown, Conn.
University of Connecticut—Class of 1978
Pre-Med: Cornell University
Parent: Nicholas S. Ranno

Warren S. Zwecker, 131 Bulkley Drive, Fairfield, Conn.
Boston University School of Medicine—Class of 1978
Pre-Med: Dartmouth College
Parent: Benedict Zwecker

Resignations, Appointments, Etc.

(a) *Editorial Committee of Connecticut Medicine:* It was VOTED to accept with regret, and thanks for past service, the resignation of Frederick W. Hehre, New Haven, as a member of the Committee. It was further VOTED to accept the resignation of Peter H. Gott, Lakeville, from membership on the Committee.

(b) *Liaison Committee with the Connecticut Bar Association:* It was VOTED to restore to membership on the Committee Harry P. Engel, Bridgeport, it being learned that it was Dr. Engel's intention (12/19/74) to resign only as chairman of the Committee.

(c) *Alternate Delegate, U.S. Pharmacopeial Convention:* It was VOTED to appoint Pasquale J. Costa, Norwich, as Alternate Delegate to the subject Convention, which meets on 3/22/75. The Delegate is James E. O'Brien, Hartford.

(d) *Committee on Drug Abuse Education:* It was VOTED to accept with regret the resignation of James D. McGaughey, III, Wallingford, as a member of the Committee.

(e) *Task Force on Collection of Health Statistics:* It was VOTED to nominate Stuart Ragland, Jr., Colebrook, to serve as a CSMS representative on a subject Task Force which is being formed at the request of the Commissioner of Health, Dr. Douglas S. Lloyd. The Task Force will be appointed by the Commissioner and will be headed by Mrs. Virginia Connolly, a State Representative, and Dr. Fred Hyde, a Vice President of the Connecticut Hospital Association.

Further Discussion of Delay in Medicaid Payments

It was VOTED to accept for filing two communications as follows: (a) A letter from Governor Grasso, expressing thanks for bringing the subject delay to her attention and pledging that "This problem is one that I will direct the new welfare commissioner to deal with after my administration assumes office on January 8, 1975."; (b) A report filed by Leo P. Giardi, Hartford, chairman of the CSMS Liaison Committee with the Welfare Department and a member of former Commissioner Norton's Medical Advisory Committee, which did not indicate that appreciable progress has been made via his contacts with the Commissioner and staff toward eliminating the subject delay. It was further VOTED to acknowledge Governor Grasso's letter and to express appreciation to her for her interest in the problem and her stated intention to take steps to try to resolve it.

Admission Certification of Hospitalized Medicare-Medicaid Patients

It was VOTED to accept for filing further information (from 12/19/74) concerning the HEW Department's regulations, published in the *Federal Register,* which are scheduled to be implemented on February 1, 1975 and call for an admission certification program to be carried out by hospitals. Observing that such certification will eventually be a regular function of the area PSROs, although they are not yet prepared to perform it, the Council VOTED to inform the Secretary of HEW, the AMA and other interested parties that the Society voices strong objection to the forced implementation of the subject regulations on February 1 on the grounds that such premature implementation may jeopardize the orderly development of PSRO planning in Connecticut's four PSRO areas, and urge that its implementation be deferred.

Reports—Fiscal Subcommittee

It was VOTED to receive and act upon a series of reports of the Fiscal Subcommittee as follows:

(a) *28th National Rural Health Conference, Roanoke, Va., 3/20-21/75:* To approve a recommendation of the Subcommittee that Gaert S. Gudernatch, Sharon, be reimbursed in an amount of up to $300 for out-of-pocket expenses incurred by his attendance at this Conference as a representative of the Society (attendance approved, 12/19/74).

(b) *Group Air Travel to Honolulu Meeting of AMA, 11/29 - 12/4/75:* To approve a recommendation of the Subcommittee that CSMS Staff, in cooperation with staff personnel of other New England state medical societies, be authorized to implement a proposal to arrange group air flights to Hawaii for members wishing to attend the subject meeting, and that $100 be allocated to cover the mailing costs of promotional materials concerning such group flights. (AMB 1/1/575 "B")

(c) *Delegate to U.S. Pharmacopeial Convention, Washington, D.C., 3/22/75:* It was VOTED to authorize James E. O'Brien, Hartford, or his alternate, Pasquale J. Costa, Norwich, to attend the subject Convention, and it was further VOTED to approve a recommendation of the Subcommittee that authorization be given for reimbursement of the delegate *or* alternate delegate in the amount of up to $175 for out-of-pocket expenses incurred by such attendance.

Reports—Committee on Public Health

(a) *Concerning State Health Department Flyer on New Program on Lead Poisoning:* It was VOTED to approve a recommendation of the Committee that the Council endorse a Health Department flyer on lead poisoning prevention and screening which is being prepared for distribution to all physicians in Connecticut. The action authorizes the Health Department to note "Endorsed by the Connecticut State Medical Society" on the flyer.

(b) *Communication to Governor Grasso:* It was VOTED to disapprove a proposal of the Committee that the Council make specific recommendations to the Governor concerning departmental appointments, and it was further VOTED that the Chairman of the Council extend an invitation to the Governor to consult with the Council at any time on matters involving health and medical care for the people of Connecticut and regarding medical and health care decisions which are hers to make.

HEW "Maximum Allowable Cost" Drug Reimbursement Program

It was VOTED to receive as information the January issue of the Staff-prepared "Council Capsules," in which were featured an analysis and critique of the recently-announced subject reimbursement program which HEW proposes to implement by regulation. Concluding that the implementation of such a program would result in mandatory generic prescribing, repeal of existing anti-substitution laws at state level and, in general, have an adverse effect on the quality of medical care of the elderly (Medicare) and the poor (Medicaid), it was further VOTED that Staff convey to the Secretary of HEW, the Food and Drug Administration, the AMA, Connecticut Senators and Congressman, and others concerned, these conclusions of the Council and urge that HEW abandon such program. The program is based on the "therapeutic equivalency" of multi-source drugs theory—a theory that has been discredited over and over by pharmacology experts and, most recently, by a "blue ribbon" panel of experts appointed by the Office of Technology Assessment.

Special Report—President, CMI

By invitation of the President, Dr. Root, James D. Kenney, New Haven, President and Treasurer of the Connecticut Medical Institute, joined the Council to make a verbal presentation concerning a problem which is being faced by the Institute and the four area PSROs as a result of the advancement of a proposal by HEW (Office of Professional Standards Review) which would establish a limited number of data storage and retrieval units throughout the country and which would require that local (area) PSROs use such regional units for data processing. At the urging of Dr. Kenney, the Council VOTED that Staff compose and send a letter to OPSR, with copies to AMA, CMI, 4 PROs and other concerned parties, stating that a Connecticut-based data processing agency should be authorized for use by Connecticut's four PSROs and presenting reasons in support of such statement. Dr. Kenney filed with Staff a sample letter to be used as a guide.

Activities Report—Commission on Hospitals and Health Care

It was VOTED to receive as information a subject report presented verbally by Sidney L. Cramer, Hartford, CSMS representative on the Commission. The bulk of Dr. Cramer's remarks were directed toward reporting the deliberations of the Commission on the establishment and beginning operation (2/1/75) of the "Pequot Medical Out-patient Treatment Center" in Groton. He reported that, contrary to his personal recommendation, the Commission had given its approval to the Center, its medical program and the method and amount of the charges to be made for services rendered; i.e., for a regular visit the charge will be $25 ($12 for a physician's service and $13 for services provided by the Center). Dr. Cramer expressed disappointment that no New London County physicians had appeared at the Commission hearing to testify. He noted also that the Norwalk Hospital has plans to initiate an ambulatory care plan within the hospital and expressed hope that staff and area physicians would attend the Commission's hearing on the plans if they held views concerning same.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on January 15, 1975. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

1975 ANNUAL MEETING
CONNECTICUT STATE MEDICAL SOCIETY

APRIL 30, MAY 1, 1975—HARTFORD HILTON HOTEL—HARTFORD

WEDNESDAY, APRIL 30—HOUSE OF DELEGATES MEETING

THURSDAY, MAY 1—SCIENTIFIC PROGRAM & SECTION MEETINGS

HIGHLIGHTS OF SCIENTIFIC PROGRAM

SYMPOSIUM ON WHAT YOU NEED TO KNOW ABOUT BREAST CANCER—1975

Why doesn't every woman get breast cancer?
How do you find the woman with breast cancer?
How much help is the pathologist?
What about hormones?
So she has breast cancer, now what?

PLAN NOW TO ATTEND

BOOK REVIEWS

BLUE CROSS, WHAT WENT WRONG—By Silvia A. Law: Yale University Press; $8.95; 246 pp.

Reviewed by Sidney L. Cramer, M.D.

Though the polls tell us differently, there is abroad in the country today, the persuasion that there does exist a "crisis in health care." This book reinforces that persuasion.

In a most scholarly and careful way, the author has researched the relationship of Blue Cross to hospitals, Medicare and Medicaid and without invective or shrill succeeds in arousing the reader to demand that such blatant subversion of the original purpose of Blue Cross be stopped and not be repeated.

To the uninitiated, it truly is a shocker. However, to those of us who have been close to hospitals and their budgets, some of the information is neither startling nor new. The book documents in detail, what many others have been claiming for years and gives publicity to those long-standing gambits between hospitals and Blue Cross which have been recognized as not in the public interest, and yet seemingly impossible to correct.

The "professional" (medical) come in for their share of blame, but one must be within the inner circle of medical affairs to know how little impact protests by physicians have had on hospital administrators and their boards of trustees; how little control physicians have over reimbursement for hospital services and "reasonable hospital" costs. The reviewer does not mean to absolve the medical profession of all responsibility, but offers the foregoing observations to mitigate the sweeping charge by Professor Law that the "professional elite" has failed to try to meet the public need.

As long as the author continued to present hard and irrefutable evidence of Blue Cross failures, she rendered a magnificent service because it reached us at a time when some change in our health system appears inevitable. One could wish, however, that she had ended the book with the conclusions based on the evidence she presented. This reviewer found her strong advocacy of the Kennedy-Griffith Health Security Bill to constitute a rather unfortunate encore to an excellent main performance. Her choice of plan for national health insurance has been characterized by experts in both private and public sectors as "too much too soon," and while it might serve to do away with "Bad, Bad Blue Cross," it might simultaneously do away with many of the features of our present health care system which are generally acknowledged to be good.

Professor Law has done a thorough job of diagnosing "What Went Wrong" with Blue Cross. The quality of the sections dealing with her proposed remedy suffer by comparison.

Reprinted from The Hartford Courant.

WHEN YOU MOVE—LET US KNOW!
WE WANT YOU TO BE SURE TO GET
THE NEXT ISSUE OF
CONNECTICUT MEDICINE

BLOOD DISEASES OF INFANCY AND CHILDHOOD by Carl H. Smith, M.A., M.D. with editorial assistance of Denis R. Miller, M.D. The C. V. Mosby Company, St. Louis, Third Edition with 175 illustrations, 874 pp. No price given.

Reviewed by Stuart C. Finch, M.D.

Dr. Carl Smith published his first complete text in the field of hematology only 13 years ago. In order to keep abreast of the rapid advances in the field this text already is in its third edition. There are 1,200 new references and many new high quality illustrations in this text of 874 pages. The book is remarkably contemporary and complete, especially in the areas which are peculiar to pediatrics. The major revisions relate to erythrocyte enzymes, leukocyte function, RH immunization, amminocentesis, therapy of leukemia and lymphoma, and disorders of blood coagulation. The sections on therapy are detailed with excellent documentation. Detailed hour by hour or day by day instructions are described for some of the more complicated problems. If one is to have any criticism of the book, it might be that there is too much detail in certain sections which does not make for easy reading. It was written by a pioneer and scholar in the field whose untimely death prior to publication has deprived us of a man of great wisdom and dedication. We are fortunate, however, to have this fine hematology reference which will serve to set high standards for future texts in the field of pediatric hematology. This book remains the bible of pediatric hematology and every pediatrician should have a copy.

BOOKS RECEIVED

The receipt of the following books is acknowledged, and this listing must be regarded as sufficient return for the courtesy of the sender. Books that appear to be of particular interest will be reviewed as space permits.

Handbook of Obstetrics and Gynecology. Fifth Edition. Ralph C. Benson, M.D. 770 pp. Illustrated by Laurel V. Schaubert. California: Lange Medical Publications. 1974. $8.00.

The Right to Die: Decision and Decision Makers. Group for the Advancement of Psychiatry. 79 pp. New York: Jason Aronson. 1973. $7.50.

Clinical Perinatology. Silvio Aladjem, M.D. and Audrey K. Brown, M.D. First Edition. 492 pp. with 135 illustrations. St. Louis: The C. V. Mosby Company. 1974. $39.50.

Myocardial Metabolism. Eugene Braunwald, M.D. 215 pp. Supplement III. New York: The American Heart Association, Inc. 1974. $6.00.

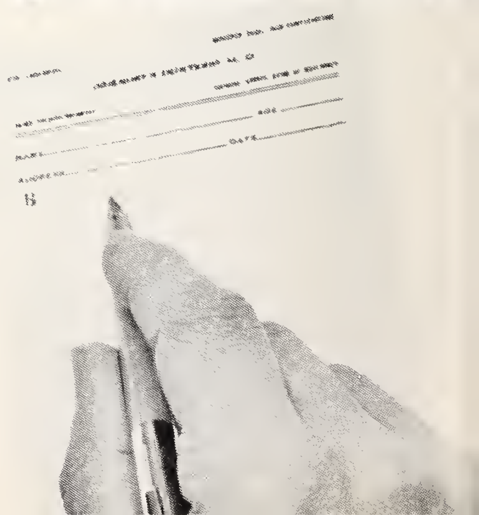
Spinal Deformity in Neurological and Muscular Disorders. First Edition. The C. V. Mosby Company. 1974. $29.50.

General Ophthalmology. Daniel Vaughan, M.D. and Taylor Asbury, M.D. Seventh Edition. 334 pp. Los Altos. Lange Medical Publications. 1974. $9.50.

Cardiovascular Surgery 1973. Edited by John Hines Kennedy, M.D. 276 pp. New York. The American Heart Association. 1974. $5.00.

Cardiac Hypertrophy and Cardiomyopathy. Edited by Jules Cohen, M.D. and Pravin M. Shah, M.D. 223 pp. New York. The American Heart Association. 1974. $5.00.

Bioequivalenc



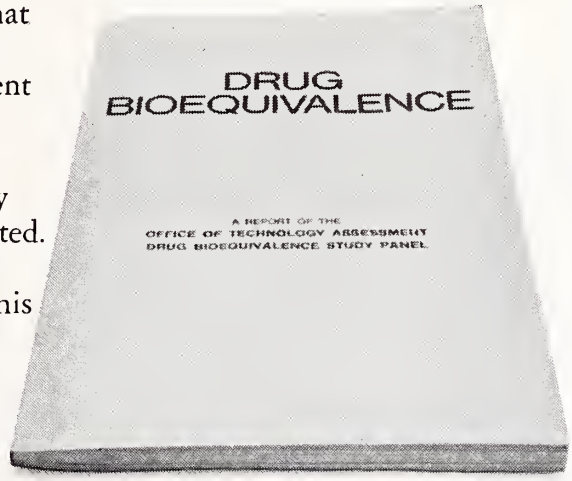
the weight of scientific opinion:

If the pharmacist substituted a chemically equivalent drug for the one you have specified for your patient—could you be certain of that product's safety and effectiveness simply because the chemical content was the same?

Definitely not, unless bioequivalence tests and other quality assurance checks had been conducted. The pharmaceutical industry and many scientists have maintained this position for years, but others have questioned it. Now the Office of Technology Assessment of the Congress of the United States has reported on the issue in its Drug Bioequivalence Study.*

Here are a few definitive statements in the O.T.A. report:

"...the problem of bioinequivalency in chemically equivalent products is a real one. Since the studies in which lack of bioequivalence was demonstrated involved marketed products that met current compendial standards, these documented instances constitute unequivocal evidence that neither the present standards for testing the finished product nor the specifications for materials, manufacturing process, and controls are adequate to ensure that ostensibly equivalent drug products are, in fact, equivalent in bioavailability.



DRUG
BIOEQUIVALENCE

A REPORT OF THE
OFFICE OF TECHNOLOGY ASSESSMENT
DRUG BIOEQUIVALENCE STUDY PANEL

"While these therapeutic failures resulting from problems of bioavailability were recognized and well documented, it is entirely possible that other therapeutic failures and/or instances of toxicity that had a similar basis have escaped attention."

The Pharmaceutical Manufacturers Association supports federal legislative amendments that would require manufacturers of duplicate prescription pharmaceutical products, subject to new drug procedures, to document:

(a) chemical equivalence; and (b) biological equivalence, where bioavailability test methods have been validated as a reliable means of assuring clinical equivalence; or (c) where such validation is not possible, therapeutic equivalence.

In addition, the PMA supports federal legislation that would require certification of all manufacturers of prescription products before they could start in business, annual inspections and certification thereafter, and strict adherence to FDA regulations on good manufacturing practices.

The overall quality of the United States drug supply is excellent. But only a total quality assurance program, envisaged in these and other policy positions adopted by the PMA Board of Directors in 1974, can bring about acceptable levels of performance by all prescription drug manufacturers and thereby assure the integrity of your prescription...

P·M·A

Pharmaceutical Manufacturers
Association
1155 Fifteenth Street, N.W.
Washington, D.C. 20005

*Copies of the complete report on Drug Bioequivalence may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

protecting the integrity of your prescription

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiry of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511, (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine.*

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

Emergency Room: Six listings of opportunities in Connecticut hospitals available through the Physician Placement Service.

Emergency Room: Physician to join Wesson Emergency Associates, Inc., Alvin J. Keroack, M.D., 140 High Street, Springfield, MA. 01105.

Internal Medicine: Fourth board certified internist to join group in eastern Connecticut shore community. Community hospital. Send resume to CSMS.

Internal Medicine: Prepaid medical plan serving greater New Haven.

Internal Medicine: Board qualified internist to join three man primary care group. Write Charles R. Williams, M.D., 325 Reef Road, Fairfield, CT. 06450.

Otolaryngologist: Board qualified ENT associate needed. Serving central Connecticut. Contact: Irving Guttenberg, M.D., 219 West Main Street, Meriden, CT. 06450.

Pediatrician: Part time. Greater New Haven area. Contact: Carlos B. Zilveti, M.D., Director of Maternal and Child Health Dept. of Health, One State Street, New Haven, CT. Tel.: 652-0151, ext. 437 or 438.

Pediatrician: Associate needed in Cheshire area. Send resume to CSMS.

Health Director: For City of New Haven, Connecticut, to give leadership to traditional programs and innovative direction for community health services. Staff of 135, including Deputy Director in charge of Business Administration. Min. requirements: M.D. and M.P.H. with 5 years experience. Send resume and salary requirement to Peter H. Feriola, Personnel Director, 200 Orange Street, New Haven, Connecticut 06510. Equal opportunity employer.

OB/GYN: Board certified OB/GYN seeks associate to join busy solo practice in large city in CT. Must be Board certified or eligible. Ability to speak Spanish essential. Salary then partnership. Send resume to B.C. c/o CSMS.

Pediatrician: Need for pediatrician in Southbury area. Contact CSMS.

Thoracic and General Surgery: Board certified associate needed for group practice. Write NT. CT. CSMS.

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

(If no name is listed, contact the Physicians Placement Service)

Internal Medicine: Board certified. Desires Western Connecticut. Torrington - Danbury area. Group or associate practice. 29 years old. Available mid 1975. Presently in U.S. Navy. Bruce A. Sobin, M.D., 2121 W. Main Road, Portsmouth, Rhode Island 02871.

Cardiology: Available July 1975. Group or Associate Practice. Board certified. Prefers clinical cardiology with limited general medicine. Michael S. Bensman, M.D., 4360 Baychester Avenue, Bronx, N.Y. 10466.

Internal Medicine—Cardiology: Board eligible. Available July 1975. Mass. license and F.L.E.X. Group or Associate Practice desired. Age 35. Married. Formerly on medical faculty in Yugoslavia. Presently fellow at Boston City Hospital. Zeljko Freiberger, M.D., 47 Fenno Rd., Newton Centre, MA. 02159.

Internal Medicine: Board eligible. Conn. license. Group, Associate, Institutional or Industrial Practice. Presently at Bridgeport Hospital. Available July 1975. M. Rama Chandran, M.D., 1700 Broadbridge Avenue, Stratford, CT. 06497.

Internal Medicine—Cardiology: Board eligible. New York license. Desires medium or small community in Group or Associate Practice. Primary care. Presently at Montefiore in N.Y. Elliot M. Rudnitzky, M.D., 3450 21 Wayne Ave., N.Y., N.Y., 10467.

Internal Medicine: Desires position as house physician or in emergency room. F.L.E.X. to be taken in June 1975. Available July 1975. 32 yrs. old. Presently in hepatology residency at N.J. College of Medicine. K.F. M.D. c/o CSMS.

Internal Medicine: Certified. ABIM. Presently holds full time academic appt. in oncology. Desires part time in hematology and oncology. Connecticut license. Mark A. Tuckfelt, M.D., 36 Florida Hill Road, Ridgefield, CT. 06877.

General Medicine and Infectious Diseases: Available July 1975. Board eligible. Passed F.L.E.X. 32 years old. Presently fellow at University of South Carolina. Mohammad A. Khan, M.D., 1175 Mathis Ferry Rd., Apt. E-2, Mount Pleasant, S.C. 29464.

Internal Medicine: Cardiology. Board Certified. Presently in Air Force. Group or associate practice. Available mid 1975. Richard F. Gordon, M.D., 109-A Birch Circle, Elgin Air Force Base, Florida 32542.

Internal Medicine: Board eligible, Connecticut license. Gastroenterology. Desires group of general internists with subspecialties. Available July 1975.

Internal Medicine: Board eligible. Solo or industrial medicine. Available July 1975. New York and Connecticut License. 31 years old. Peter Sereny, M.D., 353 East 17th Street, 25C., New York, New York 10003.

General Medicine: Medium or small community. Available June 1975. Completing 1 year of IM residency. Desires primary care in community needing a physician. Bowdoin, Rochester Medical, University of Texas internship and residency. Allan Currie, M.D., 6523 Spring Well, San Antonio, Texas 78249.

General Internal Medicine: Connecticut license. Board certified. Part or full time. Broad experience. Former solo practitioner. Industrial and teaching experience. Relocating in Connecticut. for semi-retirement. I.A. Schiller, M.D., 74 B. Dakota Lane, Stratford, CT. 06497. Tel.: 375-0398.

Continued on page 202

In Memoriam

Margold, Allen M., Vermont Medical School, 1925. Dr. Margold was a practicing urologist in the Fairfield area since 1932. During WW II, Dr. Margold was a commander in the U.S. Navy, serving in Europe and the Pacific. He was director of medical education and director of surgery at Norwalk Hospital. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Margold died January 3, 1975, at the age of 73.

Simmons, Eric M., Yale Medical School, 1923. Dr. Simmons was a general practitioner in the Hartford area since 1923. He was a second lieutenant in the infantry in WW I, and served as chief resident physician at the Waterbury Hospital in 1925. Dr. Simmons was also a medical examiner for Southington for many years. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Simmons died January 9, 1975, at the age of 78.

Spence, James K., University of Pittsburgh, 1954. Dr. Spence was a practicing internist and cardiologist in the Fairfield area since 1965. He was on the staff of Danbury Hospital and was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Spence died December 27, 1974, at the age of 53.

Sutula, Stanley, Jr., Jefferson University, 1965. Dr. Sutula was a general practitioner in the Hartford area since 1968, and worked for the State Council on Tuberculosis. Hospital Care and Rehabilitation. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Sutula died December 27, 1974, at the age of 35.

CLEAR YOUR MEETING DATES THROUGH CSMS

Society members are urged to take advantage of the CSMS service which maintains a calendar of all major medical meetings in the state.

Far too often, there is a conflict in the dates of these meetings, which involve many of the same medical leaders. It is unfortunate, for instance, when a major county hospital holds a meeting at the same time as an annual meeting of the county Association or the House of Delegates of the State Medical Society.

To avoid these conflicts physicians are asked to call the CSMS office, listing the dates of their meetings and to check to see if any other events have already been scheduled for the same time.

OBITUARY

Andrew O. Laakso, M.D.
1911-1974

Andrew O. Laakso, M.D., was born in Korpilahti, Finland on May 27, 1911. His parents, Andrew J. and Hilma E., returned to the United States when he was about two years old.

After attending schools in Plainfield, he was graduated from Tufts University in 1933 and from Cornell University Medical College in 1937. His internship was served at Hartford Hospital and began practice in Danielson in 1939.

Soon after he joined the staff of the Day Kimball Hospital in Putnam, and for a short while the Windham Memorial Hospital in Willimantic. He was chief of surgery at Day Kimball until 1972 when he resigned.

In 1948, he become associated with Drs. G.M. Chartier and J.F. Jones in a partnership practice known as the Danielson Clinic until his sudden death on November 17, 1974 at his home.

Dr. Laakso was honorary vice counsel of Finland since 1955. The president of Finland had also conferred on him the honor of Knight First Class of the Order of the Lion of Finland.

He leaves his wife, Anne Betters Laakso, a son, Andrew Gregory of Dayville, and two granddaughters.

G. M. Chartier, M.D.

PHYSICIAN PLACEMENT SERVICE (Cont.)

Continued from page 200

General Surgery and Gynecological Surgery: Certified in OB/GYN. Board eligible in general surgery. Tufts Medical School. 44 years old. Married. Prefers group practice. Lawrence J. Phalone, M.D., 12538 Leavenworth Street, Omaha, Nebraska 68154.

General Surgery: Board certified. Also interested in general medicine with surgery. Presently in practice. 36 years old. Graciano P. Sison, Jr., M.D., P.O. Box 364, Willsboro, N.Y. 12996.

Neurology: Board eligible. Available July 1975. 32 years old. Experienced in EEG, EMG. Solo, Group or Associate Practice. Currently serving in armed forces. Trained at Louisiana State University Medical Center. JES MD, c/o CSMS.

Neurology: Board eligible. Available July 1975. Group or Associate Practice. Harvard, University of Chicago Medical School, University of California in San Francisco. 32 years old. Married. 2 years experience in USPHS. Richard M. Lowenthal, M.D., 1459 Fifth Avenue, San Francisco, CA. 94122.

Ophthalmology: Board certified. 31 years old. Solo, group or associate practice. Large or medium-sized city. Available July 1975. Presently with U.S. Public Health Service Hospital. Melvyn Damast, M.D., 1351 Bay Street, Apt. 12, Staten Island, New York 10305.

Orthopaedic Surgery: Board eligible as of July 1975. Available summer of 1975. Johns Hopkins, George Washington University, St. Vincent's and Downstate Medical Centers, N.Y.C. Age: 32. Completed two years of active service. Married. DeWitt C. Brown, III, M.D., 2736 Independence Avenue, Riverdale, N.Y. 10463.

Pathology: Board certified C.P. and H.P. Group or Associate Practice. Large or medium sized community. Available July 1975. Two years with U.S. Naval Hospital. Antonio Tamara, M.D., 1738 Aberdeen Road, Baltimore, MD. 21234.

Pediatrics: Board eligible. Group or associate practice. Available July 1975. 29 years old. N.Y.U. Medical. Bellevue and Boston City Hospitals. Melvin I. Katz, M.D., 8 Hallmark Gardens, Burlington, Massachusetts 01803.

Physician's Asst.: Available in June 1975. Currently enrolled in program. 30 years old. Four years in U.S.N. Hospital. Certified respiratory technician. Desires position with primary care or specialty group. James E. Thompson, 1011 West Avenue, Elyria, OH. 44035.

Psychiatry: Board eligible. Available July 1975. Group or institutional practice. 30 years old. Presently in the Navy. William A.F. Woods, M.D., 6060 Churchland Blvd., No. 83, Portsmouth, Virginia 23703.

Surgery—General: General and Vascular. Trained in colonoscopy. 28 years old. Available July 1975. Board eligible. Allen B. Davis, M.D., Oak Hill Apt. E-211, Penn Valley, Pennsylvania 19072.

Surgery—Orthopaedic: General orthopaedics with reconstructive surgery. Available mid 1975. Harvard trained.

Surgery—Orthopaedic: Group or associate practice. Available July 1975. Board eligible. New York license. Tufts, Albany Medical College. Upstate Medical Center, Syracuse. Robert M. Sheridan, M.D., 18 Pickwick Road, Dewitt, New York 13214.

Thoracic Surgery: General Thoracic and Cardiac surgery. Group or associate practice. Board eligible. 35 years old. New York Medical College, Bellevue and Boston City Hospitals. Jack C. Lee, M.D., 860 Harrison Avenue, Apt. 805, Boston, Massachusetts 02118.

Urology: Board eligible. New Jersey license. 36 years old. Married. M. F. Abidin, M.D., 227 Cambridge Avenue, Jersey City, New Jersey 07307.

Urology: Available July 1975. Native of Waterbury. Ohio State Medical School. Board eligible. Group, solo or associate practice. Harold T. Collins, M.D., 1054 West Chalet Drive, Mobile, Alabama 36608.

Urology: Available July 1975. Board eligible. Associate, group or solo practice. Harvard and University of Vermont Medical School. Joseph M. DeCenzo, M.D., Woodbine Road, Shelburne, Vermont 05482.

Urology: Board eligible. 30 years old. Duke. Cornell-N.Y. Hospital. University Hospital Ann Arbor. Group or associate practice. Stephen A. Koff, M.D., 12260 Stone Drive, Ann Arbor, Michigan 48105.

Urology: Available July 1975. Tufts and Cornell-N.Y. Hospital. 32 years old. Solo, group or associate practice. Harvey A. Koniasberg, M.D., 445 E. 68th Street, New York, N.Y. 10021.

Urology: Board eligible. Solo or associate practice preferred. Yale. Columbia Medical School, Darmouth-Hitchcock Hospital and Medical College of Virginia. 34 years old. Presently in service. Available June 1975.

Urology: Board eligible. 31 years old. Available July 1975. New York and California licenses. Solo or associate practice. Columbia and Downstate Medical. Presently at Montefiore Hospital. Joel W. Goldsmith, M.D., 5700 Arlington Avenue, New York, N.Y. 10471.

PLEASE MARK YOUR CALENDAR

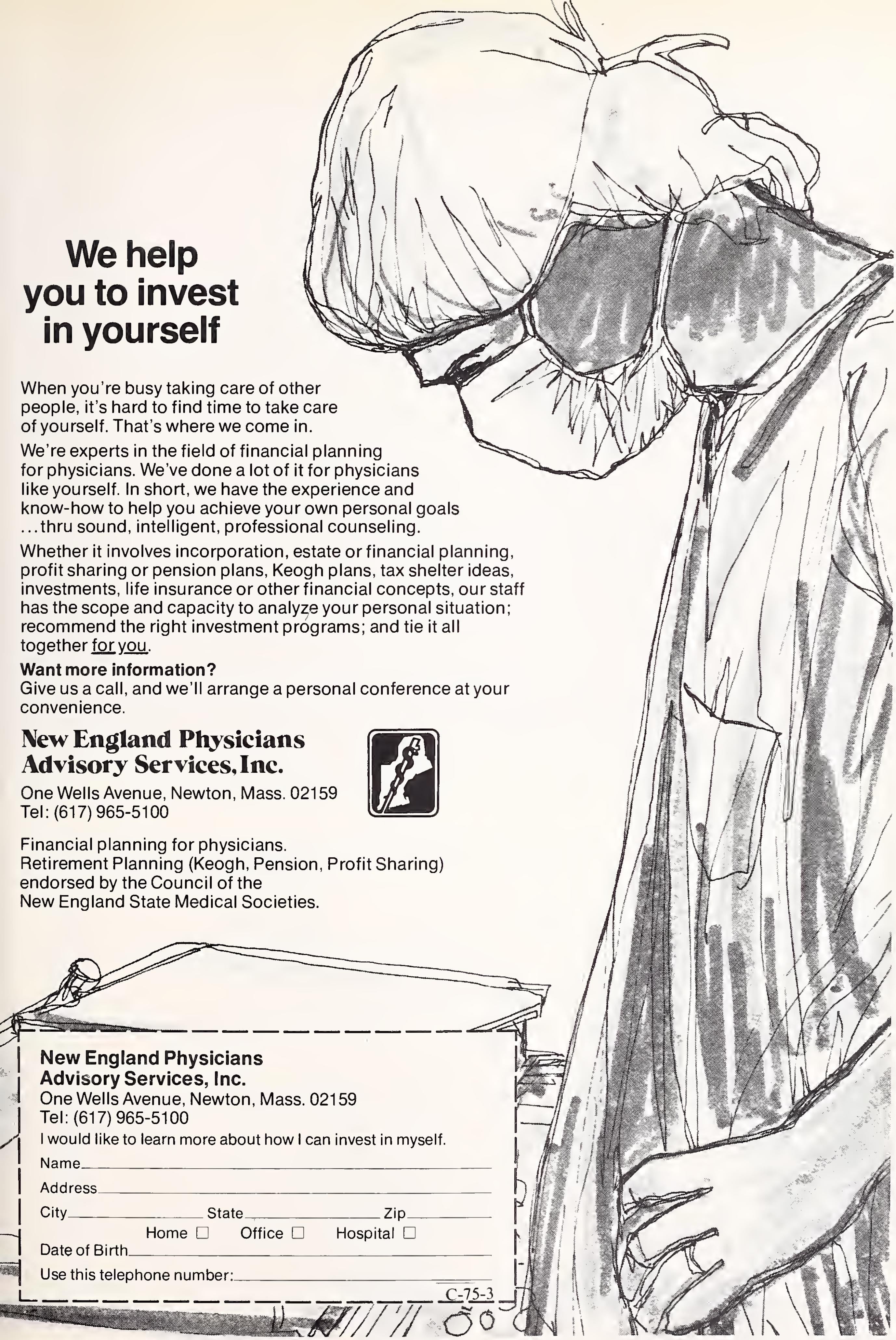
183rd CONNECTICUT STATE MEDICAL SOCIETY

ANNUAL MEETING

To Be Held At The
Hartford Hilton Hotel, Hartford

APRIL 30, MAY 1, 1975

Plan Now and Save the Dates



We help you to invest in yourself

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Connecticut Medicine

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Management of Cancer of Unknown Primary

David S. Fischer, M.D., F.A.C.P.

Metastatic malignancies are hard enough to treat when their site of origin is known; they become far more difficult to manage when the primary site is unknown. Thorough work-up combined with some knowledge of the natural history of malignancies and previous experiences with similar problems is always helpful in dealing with this common situation when it occurs.

In trying to evaluate the problem of the unknown primary malignancy, it would be helpful to have some definition of just what we are talking about. Unfortunately, there is no general agreement in the literature about such a definition. Johnson and colleagues[1] at the University of Wisconsin summarized their experience in 185 cases which represent 2.3% of their total registry cases of 8,197 reported between 1955 and 1960. They point out that eventually, particularly at autopsy, many such lesions are identified as to the primary site, but the delayed diagnosis is of little value to the physician in the immediate management of the individual patient. Since the disease is frequently located in multiple sites, the major mode of treatment in recent years has been chemotherapy, since surgery or radiation is reserved for single lesions or for the more symptomatic of the multiple lesions. On the other hand, there have been a number of other series which have looked at the problem from a more restricted point of view than the Wisconsin group. Barry and colleagues[2] and Jesse and Neff[3] restricted their inquiry to metastatic carcinoma in cervical lymph nodes with an unknown primary lesion. Whereas Johnson was dealing with 43% adenocarcinomas and 8% squamous cell carcinomas, Barry was dealing with the reverse, 85% squamous cell carcinoma and 9% adenocarcinoma and Jesse and Neff with 47% squamous cell and 10% adenocarcinoma. Thus, in their series, surgery or radiation was the major approach.

A more recent attempt to look at the problem by Moertell and colleagues[4] was really a report of a gastroenterology group and they restricted their analysis to cases of adenocarcinoma alone. Most of these metastases were picked up in the liver and most of the patients were treated with chemotherapy. Another attempt to survey the problem from the broadest possible view was an analysis of the Kansas Medical Center registry by Holmes and Footes.[5] They analyzed the 21,000 cases of the cancer registry from 1944 to 1969 and found 784 cases, but they eliminated 98 because they were subsequently found to either have lymphoma or the primary was ultimately determined. Then they analyzed the remaining 686 patients and broke them down into histologic type and compared their survival with that of the normal population and showed that it was drastically different. The problem with this type of analysis is that it discarded the 98 most interesting patients and the reader never learned where the hidden primary was discovered.

There is no good way to treat the cancer of unknown primary. One may either find the primary and treat it according to the best methods available or else from previous knowledge of the behavior of histologic disease and their primary locations, to attempt to guess what the most likely primary is and then treat the patient according to the best therapy for that presumed primary taking cognizance of the other possibilities and attempting to cover them as well. With this introduction I would give as my definition of cancer of the unknown primary for our purposes, a cancer whose primary site is unknown at the time when the therapeutic decision must be made. It is presumed of course, that an adequate work-up has been performed before such a decision is to be made, but it is clear that such a work-up cannot be endless and cannot be conducted without regard to the patient's comfort, well-being and both the patient's and society's financial and medical assets which are necessarily limited.

In general, in an unselected series, approximately 3% of all malignancies will at the time of initial therapy be from an unknown primary. The way they present is most often related to the diagnostic armamentarium that we have at that moment at our disposal. The presenting site of the original malignancy will usually be one that is most accessible to discovery. Thus, palpable lymph nodes are perhaps the most frequent site where an unknown primary will be found. Because a malignancy in bone is very

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This paper is based on a talk given at a post-graduate symposium on "Current Concepts in Cancer Management," November 8-10, 1973 in New Haven. The symposium coordinator and editor for this article is Dr. John Marsh, Associate Professor of Medicine and Pharmacology, Yale University School of Medicine. The support of the Connecticut Division of the American Cancer Society is gratefully acknowledged.

frequently painful and because it is easily accessible to radiological diagnosis and now more recently to isotopic scan diagnosis, a site in the bone will probably be the second most common diagnostic location in a general series. The liver because it is easily palpable on physical examination and because histology can be obtained easily with a needle biopsy and because defects in perfusion by isotopic scans are easily found, the liver will be the third most common site. The lung being seen easily on x-ray and presenting with symptoms of cough, chest pain or shortness of breath is the fourth most common site of presentation. Intraabdominal tumors and ascites are usually palpable on abdominal exam and can be demonstrated by Roentgen contrast studies and they are the fifth commonest site. The brain with its neurologic changes when compressed or in other ways injured is the sixth commonest site. Finally, because the skin is easily seen and easily felt, it is another common site of unknown primary presentation. The histology that is found will depend upon where the tissue is obtained. If it comes primarily from the liver and GI tract, it will be mostly adenocarcinoma. If it comes largely from the cervical lymph nodes, it will be primarily squamous cell or epidermoid carcinoma. However, if a general series not so restricted is reviewed, the majority of cases are adenocarcinomas and an equal or smaller number may be undifferentiated or anaplastic carcinomas and a still much smaller percentage will be squamous or epidermoid carcinomas. In looking over the published literature it seems that a great deal of information that should have been available simply was not included in the articles because they tended to throw out the cases that would have been most interesting, those that were eventually diagnosed. In addition, most of the articles failed to indicate how the diagnosis was made histologically, that is, was it from a tissue section cut out of an organ or lymph node, or was it in fact a sputum cytology, a peritoneal or pleural cytology? Was it a needle biopsy of the liver or a bone marrow aspiration or a bone marrow trephine biopsy?

I decided to look at my own practice as an Oncologist because it seemed to me that a cytologist in general can seldom say more than that the tissue was malignant or benign and in the majority of cases cannot designate its site of origin. The same is probably true for bone marrow biopsies. The experienced pathologist with a needle biopsy of the liver may be able to do a better job than just diagnose malignancy versus benignity, but very often a metastatic lesion sheds its identifying marks at the metastatic site and even with a good lymph node or other tissue biopsy, the pathologist is frequently at a loss to make a definitive diagnosis as to the site of origin and sometimes even as to histologic type and simply makes a diagnosis of undifferentiated or anaplastic carcinoma.

To get some idea of what was going on in my own practice, I analyzed all those cases that were signed out as carcinoma of unknown primary and found 40 such cases in 6 years. It appeared to me from my knowledge of my own practice that I had missed a great deal and that there were a lot of cases of unknown primaries that were not so listed in the books, and accordingly we looked at those that were signed out as either pancreas or lung. Thirty-five cases of pancreas were signed out and as we looked at them carefully it was obvious that in 12 cases we were just guessing that the primary was in the pancreas and really had no data to prove it. In sixty-five cases that we had signed out as lung carcinoma, 29 were metastatic with no established primary. We have at the present time 9 cases under observation with an unknown primary for a total of 90 such cases. Of this group, 29 were adenocarcinomas, 29 were undifferentiated, 14 had the diagnosis based exclusively on a positive cytology, 6 were epidermoid carcinomas, 5 had the diagnosis based on a needle biopsy of the liver, 4 had no histologic confirmation but unequivocal evidence of metastatic malignancy that anyone would accept, 4 were diagnosed on bone marrow, 3 turned out after proper evaluation to be lymphoma and 3 were in a miscellaneous group.

In several cases a diagnosis was established by more than one modality and in each case the histologic diagnosis is listed under what I thought was the most reliable. If a standard tissue was obtained as well as cytology, I listed the tissue diagnosis; if cytology and a bone marrow were obtained, I listed the bone marrow; if bone marrow and needle biopsy of the liver were obtained, I listed the needle biopsy of the liver. Of these 90 cases, 15 eventually came to autopsy and it was found that the primary turned out to be: one in the breast, one in the ovary, one in the vagina, 3 in the lung, one cholangiocarcinoma of the liver, one carcinoma of the stomach, one in the prostate, one turned out to be a lymphoma and one was a widely disseminated medulloblastoma. Even after autopsy, 4 cases remained totally unknown as to primary, including one that we had signed out as carcinoma of the pancreas, and the only thing the pathologist could tell us with great certainty was that the pancreas was totally uninvolved. In 5 cases we eventually established a diagnosis by later biopsy or by evaluation of the evolution of the case. Two of these were in the lung, one in the thyroid, one a lymphoma and one in the pancreas. In summary then, the diagnosis was established in 20 of 90 cases of whom 9 are still living.

In analyzing their data the Minnesota group[4] attempted to look at established primaries from an adenocarcinoma. While many of their patients died and no autopsy was permitted and in many cases patients died at home or in a convalescent hospital, so that it was not practical to get autopsies, there were 42 patients in which they felt the primary site was established with reasonable certainty, either during the course of the malignant disease or at autopsy. In these 42 cases they found 16 of the pancreas, 5 in the colon, 5 in the stomach, 4 hepatomas, 2 hypernephromas of the kidney, 2 adrenals and 2 in the breast and one each at 6 other locations.

When we look at the cervical lymph node metastases, we find that most of them that are high represent tumors from the larynx or nasopharynx or the oral cavity, whereas, most of those that are in the supraclavicular area represent metastases from below the clavicle. In general, about 60% will be found subsequently to come from the head and neck area and perhpas 30 to 40% from the area below the clavicle. With diligent study about 1/3 of these will have the primary site of malignancy determined and the remaining 2/3 will not.

In a recent review of axillary metastases from an unknown primary Copeland and McBride[6] pointed out that the majority of these lesions, 19 of their 60 cases were from the breast. In the remaining 41 cases the primary site was determined in only 8 and this included one in the lung, one rhabdomyosarcoma, a fibrosarcoma, 2 carcinomas of the stomach, a neurogenic sarcoma, a case of Hodgkin's Disease and an epidermoid carcinoma of the pharynx.

Diagnostic work-up of the unknown primary obviously must be based to a reasonable extent upon the suspected primary and experience would indicate that there are some that are simply more likely than others. For example, a metastasis in the liver statistically is most likely to come from either colon, breast, pancreas, lung, or stomach. A metastasis to the peritoneal cavity would certainly come either from the ovary, the colon or pancreas; in a smaller percentage of cases from the stomach or breast. Whereas metastases to the lung can come from almost anywhere they in fact usually come from the breast, the colon or the other lung and far less frequently from the pancreas, ovary, prostate, stomach or skin (and that skin metastasis is usually a melanoma). Pleural metastases come almost exclusively from the breast and lung, although they have been known on occasion to come from melanoma, stomach, colon or cervix. Bone metastases come from the breast and prostate most often, although they also come from the lung, kidney, bladder, uterus, colon, melanoma, testes, cervix or other organs. Metastasis to the brain and to the spinal cord most commonly comes from the lung, breast or skin and rarely from the testicle, colon or other sites. Lymph nodes generally filter out metastases from their area of drainage such that cervical nodes will have tumor from the nasopharynx, tonsil, thyroid, larynx, tongue, hypopharynx and less frequently from other sites below the clavicle. In contrast the supraclavicular nodes will most frequently have tumor from the thyroid, bronchus or lung, breast, esophagus, stomach, pancreas, colon and prostate. Axillary nodes will usually have the tumor from the breast or lung. Inguinal nodes will most often have a tumor from the female genital tract, from the rectum, anus, prostate or a melanoma.

The work-up of a patient with an unknown primary must of course include a careful history of illness, a family history which often gives clues, an occupational history, social history and a meticulous physical examination (in the female an examination especially of the breast and a pelvic exam). A chest x-ray, complete blood count, urinalysis, stool, liver function studies and enzymes are also essential. When the site of the primary can be found it is best to treat it specifically. When the site cannot be found it is necessary to do the next best thing. For cervical lymph nodes with metastatic tumor a radical neck dissection is often sufficient and sometimes, depending upon the case, post-operative radiation is given in addition. For a supraclavicular node, local excision followed by radiation therapy alone is probably the best that one has to offer. In the case of a thyroid, there is some controversy whether a total thyroidectomy is necessary or whether a hemithyroidectomy is sufficient. Having seen a few tragedies from restricted surgery, I personally believe that a total thyroidectomy and a radical neck dissection on the involved side for the thyroid primary is indicated. For very large lesions, especially squamous or unclassified carcinomas bigger than 4 cms. a combination of 5,000 rads of radiation to the affected side of the neck is frequently given before surgery to shrink the mass which is then removed by a radical neck dissection converting a non-resectable lesion to a resectable one. If there are nodes on both sides of the neck that contain squamous carcinoma they are usually treated by radiation therapy alone which includes the base of the tongue and the nasopharynx area. However, if the nodes lie along the jugular vein, bilateral radical neck dissection is preferred by some authors.

An adenocarcinoma that is discovered in the liver is most often treated with 5-Fluorouracil or a combination of drugs which includes 5-Fluorouracil with an alkylating agent or one of the new experimental compounds. Metastatic disease in the peritoneum and especially ascites is more often from the ovary and is therefore treated with an alkylating agent or

5-Fluorouracil or both in combination. When the ascites is due to a pancreatic adenocarcinoma, it is more often treated with 5-Fluorouracil or with experimental drugs. Bone metastases are generally given radiation therapy for the relief of pain and to prevent fracture, and since most of them come from either breast or prostate they are treated by appropriate hormonal manipulation and/or an appropriate ablation procedure. Cancer in the lung or of the lung is most frequently treated by radiation and if appropriate later, by an alkylating agent. The Wisconsin group[7] has pointed out that even adenocarcinomas in the lung seem to respond better to an alkylating agent than to 5-Fluorouracil. Pleural metastases are generally treated by instillation of nitrogen mustard or thio-TEPA into the pleural space which is then obliterated under suction. If the pleural metastasis is from the breast, then the therapy of the breast malignancy frequently clears the pleura against recurrence. Brain metastases and spinal metastases are most frequently treated by radiation, cortico-steroid therapy or decompression by surgery. In recent years there has been some experimental work with a new group of chemotherapeutic agents that are lipid soluble and cross the blood brain barrier and the most promising seems to be either BCNU (bis-chlorethyl nitrosourea) or some of its analogs, like CCNU or methyl-CCNU.

One would hope that as we make further progress in the therapy of individual malignancies, similar progress will accrue in the therapy of the unknown primary and that with better diagnostic tools there will be fewer unknown primaries. At the present time a number of groups are approaching the unknown primary with multiple drug chemotherapy using a combination of 5-Fluorouracil, an alkylating agent such as Cytoxan, a vinca alkaloid, either Vincristine or Vinblastine, combined with prednisone to help keep the white count elevated and decrease platelet depression and a second antimetabolite such as Methotrexate. These multiple drug combinations are extremely toxic but they do cause a high incidence of objective tumor regression. I think it is yet to be determined whether they cause a prolongation of life in carcinomatous and sarcomatous disease. Further studies with these regimens will obviously be necessary. As new agents come along and go through the gauntlet of testing and prove their value in specific known primaries, they too will probably be introduced into an attempt at single drug or combination chemotherapy to broaden the spectrum and efficacy of therapy in the unknown primary. In addition to this, combined radiation and chemotherapy is again being explored after some period of neglect and it is probable that the efficacy of the combination will exceed its toxicity when done judiciously and carefully. Under these circumstances, one would hope to be able to improve the dismal prognosis and short life span of patients with an unknown primary.

PRESENTING SITE OF CANCER OF UNKNOWN PRIMARY

Site	*Wisconsin*	*Minnesota*	*N.Y. & Texas*	*Kansas*
Lymph node	23%	12%	100%	19%
Bone	21%	5%		16%
Liver	18%	56%		11%
Lung	14%	12%		13%
Intraabdominal	11%	11%		14%
Skin	7%	7%		2%
Brain	6%			9%

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Breast	1	Still Unknown	4
Ovary	1	Liver	1
Vagina	1	Stomach	1
Lung	3	Prostate	1
Medulloblastoma	1	Lymphoma	1

Diagnosis established by later biopsy:

Lung	2	Lymphoma	1
Thyroid	1	Pancreas	1

CANCER OF UNKNOWN PRIMARY

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Histologic Diagnosis	
Adenocarcinoma	29
Undifferentiated carcinoma	22
Positive cytology	14
Epidermoid cytology	6
Needle biopsy of liver	5
None	4
Bone Marrow	4
Lymphoma	3
Other	3
	90

REFERENCES

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Effects of Mithramycin and Calcitonin in Cardiovascular Complications of Paget's Disease of Bone

**Richard C. Pembrook, M.D., Chu Ho Chung, M.D.
and Alejandro P. Carvallo, M.D.**

ABSTRACT—We present a case discussion of a patient with congestive heart failure presumed to be secondary to Paget's disease and a favorable response of the heart failure to successive courses of therapy with Mithramycin and Calcitonin. We propose that these agents may be effective in treating heart failure which is due to Paget's disease of bone.

Introduction

In the century since Sir James Paget first described the disease of bone which bears his name,[1] numerous studies have been reported describing the pathology,[1-8] symptoms, and treatment.[9-21] Approximately ¾% of the adult population over 40 years of age are affected with this disease and the male-female ratio is 2:1. The disease is commonly asymptomatic and is discovered as a result of alterations in bone X-rays or serum alkaline phosphatase.[4]

The disease is characterized by an excessive rate of bone resorption and formation and an increase in the number of osteoclasts.[22] The major clinical manifestations and pathological changes have been summarized in an excellent review by Deuxchaisnes.[4] The bony changes result in severe skeletal deformities and also deafness due to sclerosis of the inner ear.[5] High output cardiac failure occurs despite the absence of arterio-venous shunting.[8 23 24] More rarely osteogenic sarcoma is encountered and usually results in early death.[9 12 21]

In the past, various forms of therapy have been tried, including salicylates, sodium fluoride, neutral phosphate, estrogens, androgens, corticoids, ACTH, and glucagon. In recent years encouraging results have been obtained with Mithramycin[9-12] and Calcitonin.[13-18 21 22] A course of Mithramycin therapy followed by a course of Calcitonin is described in our patient.

Case Presentation

The patient first entered the Providence VA Hospital on April 30, 1965 because of progressive ankle edema, increasing hat size, and deafness. At that time the patient was noted to have a broad skull with prominent temporal and occipital arteries. There was marked anterior bowing of the right tibia with warmth of the over-lying skin. A chest X-ray showed evidence of cardiomegaly, but no pulmonary congestion. Bone X-rays showed changes consistent with Paget's disease.

The patient's edema responded well to diuretic therapy on this initial admission. However, despite the use of exercise and sodium restriction, digitalis, and "loop" diuretics in massive doses, the patient was re-hospitalized nine times over the subsequent eight years for treatment of progressive heart failure. The later admissions were characterized by increasing dyspnea, bone pain, leg edema, bony deformities, cardiomegaly, and pulmonary congestion.

The patient's ninth admission occurred on February 2, 1973. Once again, dyspnea and ankle swelling were the patient's chief complaints. On examination he was found to be an acutely and chronically ill, dyspneic, and deaf 80 year old male. His blood pressure was 160/60. His pulse was 75 per minute and irregularly irregular. His temperature was 98° F. His head was markedly enlarged with very prominent temporal and occipital arteries. He had neck vein distention and a positive hepatojugular reflex. There was cardiomegaly and an apical pan-systolic murmur. His chest was markedly deformed and wet rales were heard at both lung bases. There was marked bowing and enlargement of the right tibia with increased warmth of the over-lying skin.

The laboratory findings included: A serum calcium of 10.2 mg%, a serum phosphorus of 4.2 mg%, a serum alkaline phosphatase of 360 units(K.A.) and a serum LDH of 760 units. The hemogram, serum proteins, fasting blood sugar, electrolytes, SGOT, CPK, platelet count, prothrombin time and urinalysis were all normal. X-ray of the chest showed marked cardiomegaly and congestion (Figure 5). X-ray of the skull, pelvis, and right tibia showed advanced Paget's disease (Figures 12, 13, and 14). The electrocardiogram showed atrial fibrillation. The bone scan showed gross distortion of the bony architecture with multiple zones of hyper and hypoactivity.

Clinical Course

During the initial part of the hospital stay, the patient remained in refractory heart failure despite full digitalization and the use of 480 mg. of Furosemide and 100 mg. of Spironolactone a day. After two months of this therapy and little clinical improvement the patient was started on Mithramycin.

One thousand micrograms were given daily by intravenous infusion. A total of ten doses were given over the course of the next seventeen weeks. A week after the first dose of Mithramycin, the serum alka-

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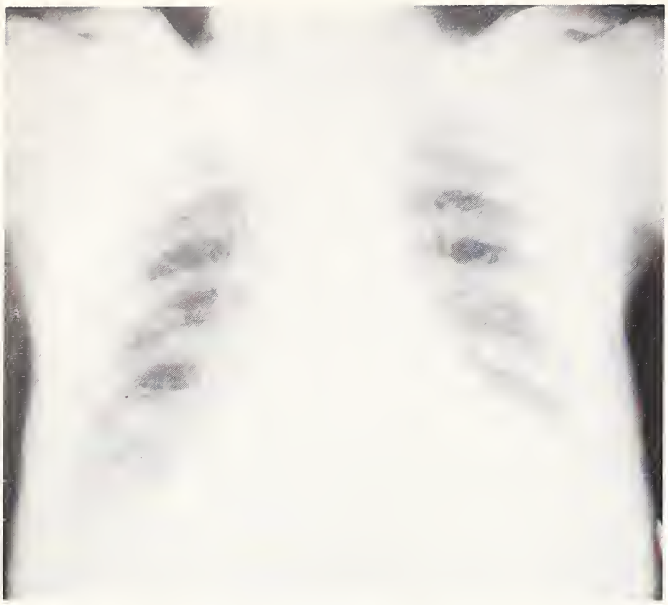

Figure 5
Before Mithramycin treatment.

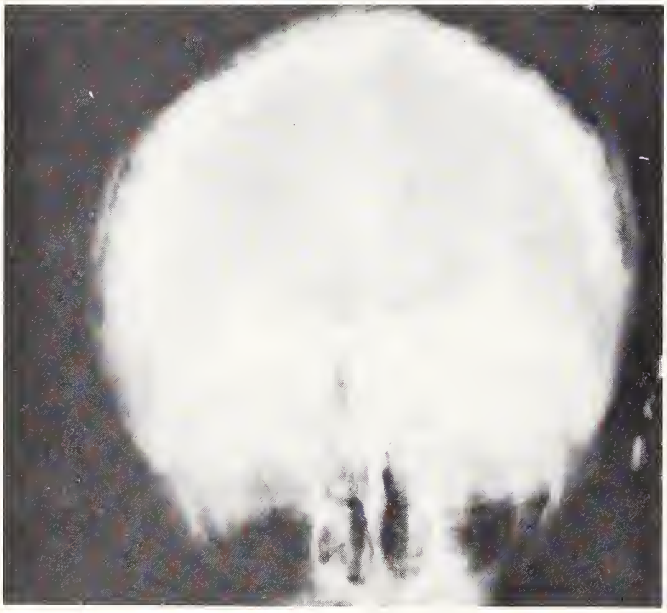

Figure 12
Skull X-Ray on admission.

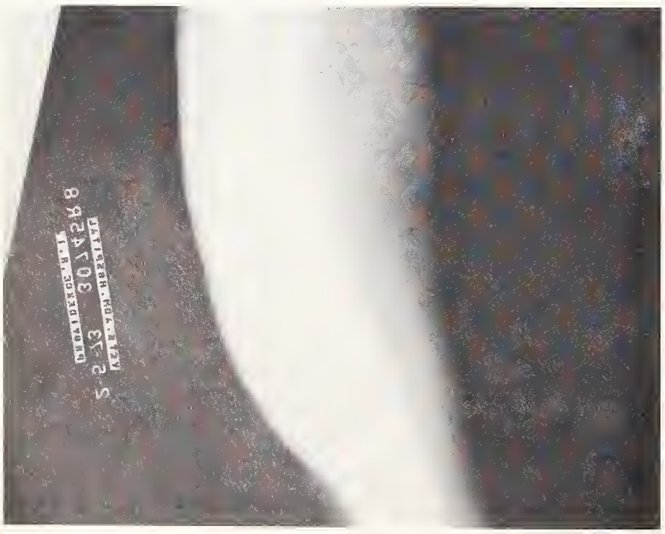

Figure 13
X-ray of the right tibia on admission.

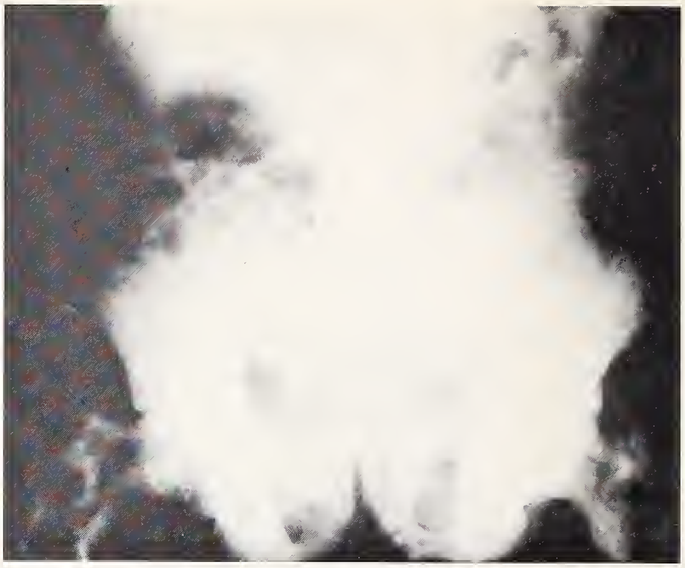

Figure 14
X-ray of the pelvic bone on admission.

line phosphatase began dropping and reached a low of 164 King-Armstrong units on the fortieth day of treatment. The serum calcium dropped from 10.2 to 8.7 mg.% and remained at that level for the next 6 months (Figure 1). The urinary hydroxyproline dropped from 375 mg/24 hours to a low of 239 mg/24 hours (Figure 2). The LDH dropped from 760 to a low of 400 units. The SGOT dropped from 70 to 44 units (Figure 4). There was no change in serum phosphorus or CPK (creatinine phosphokinase). The cardiac output determined by Fick technique dropped from 9.75 liters per minute to 4.9 liters per minute.

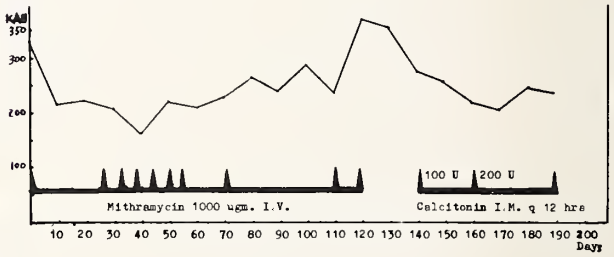

Figure 1
Serum alkalinephosphatase level during Mithramycin and Calcitonin treatment.

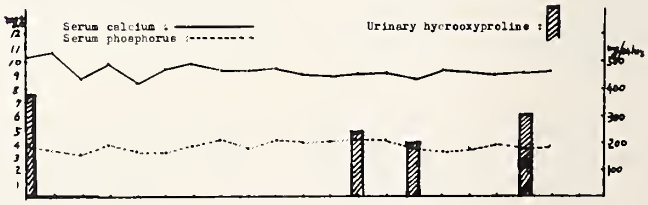

Figure 2
Serum calcium, serum phosphorus and 24 hrs. urinary Hydroxyproline level during Mithramycin and Calcitonin treatment.

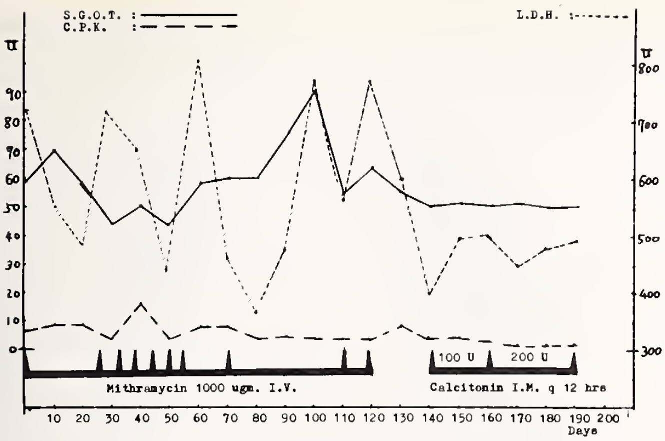

Figure 4

S.G.O.T. C.P.K. and L.D.H. changes during Mithramycin and Calcitonin treatment.

Chest X-rays showed decreased heart size and pulmonary congestion 40 days after Mithramycin was started (Figures 6 and 7).

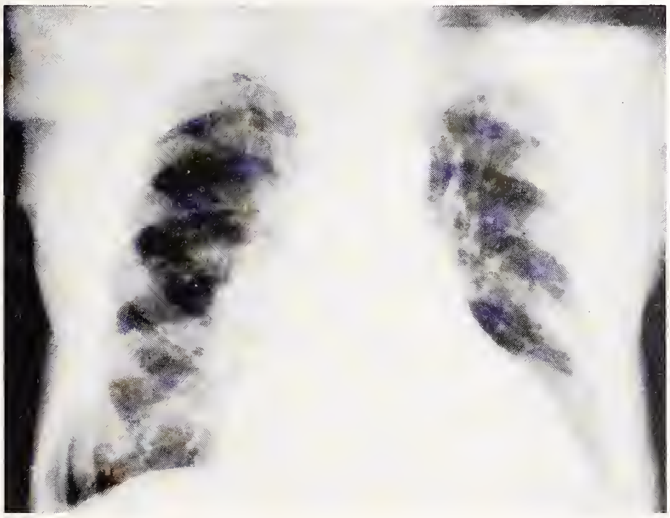

Figure 6
40 days after Mithramycin treatment.

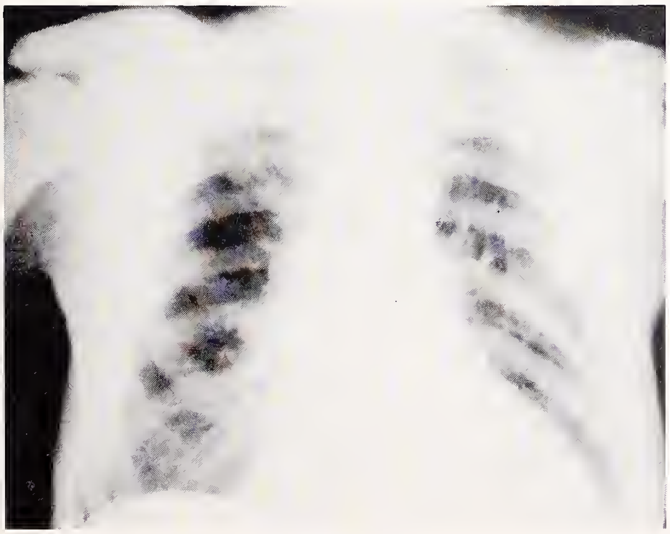

Figure 7
60 days after Mithramycin treatment.

The interval between doses of Mithramycin had to be increased to two to three weeks and the medication finally had to be discontinued altogether because of hemorrhage and thrombocytopenia (Figure 3).

After 120 days of Mithramycin therapy, the drug was stopped and signs of congestive heart failure recurred (Figures 8 and 9). Twenty days after the last Mithramycin infusion a course of Salmon Calcitonin was begun. One hundred MRC units were given intra-muscularly every 12 hours for 20 days followed by two hundred MRC units every 12 hours for 30 days.

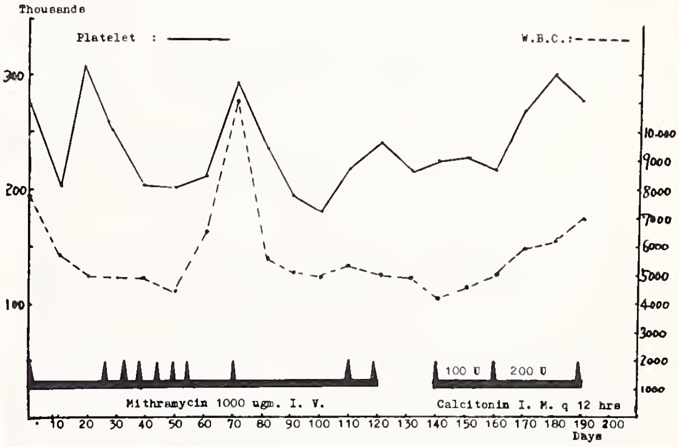

Figure 3

Platelet count and W.B.C. count during Mithramycin and Calcitonin treatment.

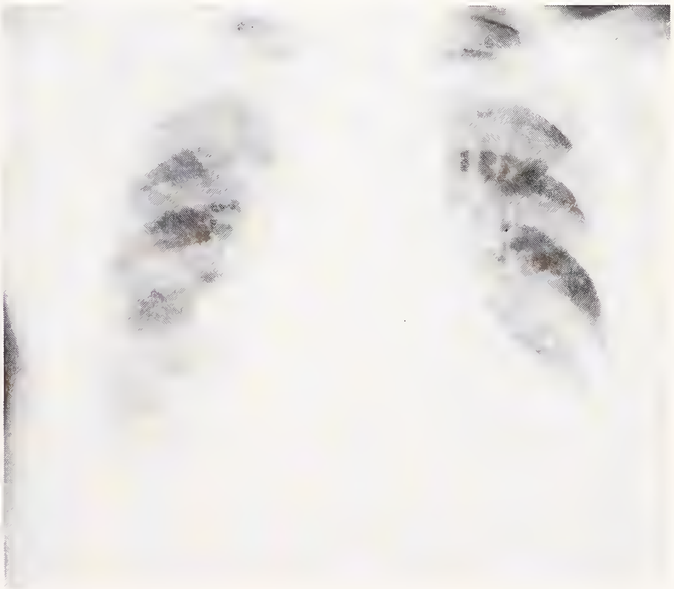

Figure 8
30 days after temporary discontinuation of Mithramycin treatment.

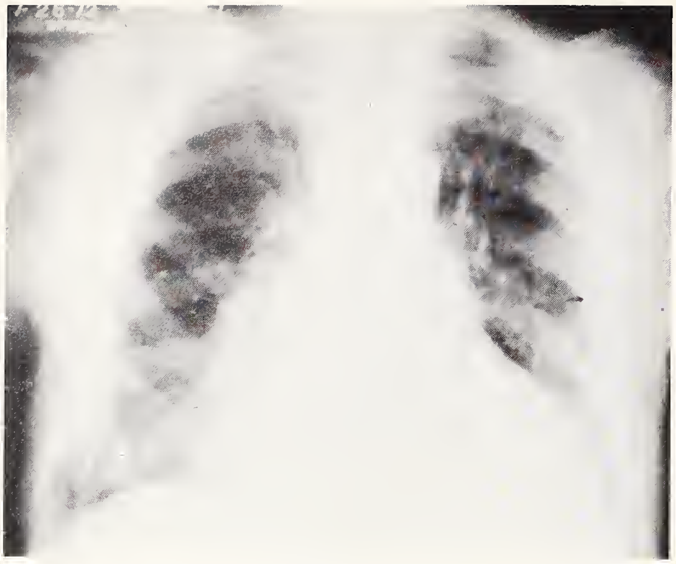

Figure 9
40 days after temporary discontinuation of
Mithramycin treatment.

The dosages of the digitalis and diuretics weren't changed during the courses of Mithramycin and Calcitonin therapy.

With Calcitonin therapy, the patient's congestive heart failure came under control once again. His cardiac size and pulmonary congestion diminished to a greater extent than at any time during his Mithramycin therapy (Figures 10 and 11). Laboratory values after thirty days of Calcitonin therapy included a serum calcium of 8.7 mg%, an alkaline phosphatase of 214 King-Armstrong units, a 24 hour urinary hydroxyproline of 318, an LDH of 450, and an SGOT of 50.

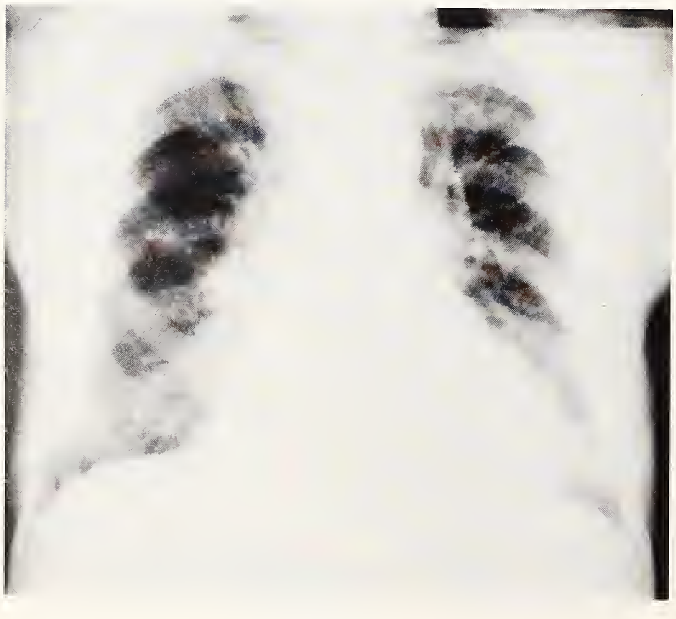

Figure 10
20 days after Calcitonin treatment.

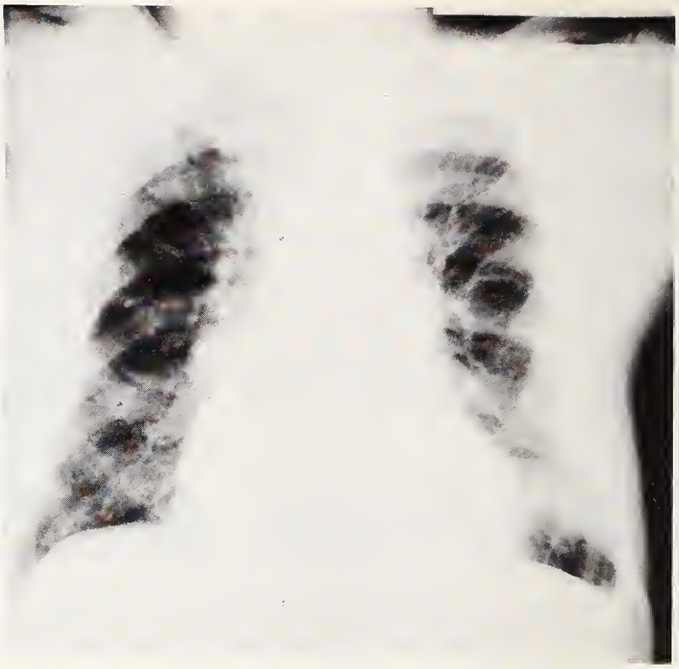

Figure 11
40 days after Calcitonin treatment.

Discussion

In 1945, Edholm reported that arterio-venous fistulaes were found in bones affected by Paget's disease.[26] However, later studies showed no bony A-V shunting in Paget's disease.[27 28]

In 1972, Rhodes used 99 m technetium labelled human albumin microspheres to demonstrate that there was no A-V shunt in Paget's disease. However, there was a twenty-fold increase in blood flow to the affected extremities as well as three-fold increase in cardiac output. These changes seemed to result from an increased capillary flow in the affected bone.[8]

Mithramycin is an antibiotic derived from a species of Streptomyces. The mechanism of action in Paget's disease seemed to be related to an inhibition of RNA formation.[25] The RNA inhibition causes decreased osteoclastic activity, reducing excessive bone resorption.[9–12] The lowered rates of bone turnover are reflected in a lowered urinary calcium and hydroxyproline excretion.[12 25]

Ryan[9 10] and Aitkin[11] have observed a drop in the serum alkaline phosphatase one week after starting Mithramycin. This drop reached a maximum at 30 to 40 days after starting treatment. Other chemical findings include a lowering of serum calcium and a change from a negative to a positive calcium balance.[10 12 25] Ryan reported a decrease in heart size after two weeks of treatment with Mithramycin. However, a cardiac output done one week post-treatment showed no change.[9]

The dosage of Mithramycin used by the various authors ranged between 15 and 25 mg/kg/day,[7–12] but the length of treatment varied. Our original schedule of a six-hour weekly infusion had to be modified because of hemorrhage and thrombocytopenia (Figure 3).

In our patient the serum calcium and phosphorus and the 24 hour urinary hydroxyproline began to decline at day 5 and reached their lowest point at day 10. However, one month after stopping Mithramycin, the urinary hydroxyproline and serum alkaline phosphatase returned to the pre-treatment level. The serum calcium and phosphorus returned to the pre-treatment level in 15 days.

Calcitonin was first proposed for the treatment of Paget's disease after it was found to inhibit osteoclastic bone resorption.[12–14,16,18,21,25] Woodhouse reported a gradual fall in serum alkaline phosphatase beginning two weeks after treatment with human Calcitonin. This decline reached its maximum at 6-7 months.[16] Later, he and Schumacher reported similar results with Salmon Calcitonin.[21]

Gershberg found that the serum calcium dropped significantly 4 to 8 hours after treatment with Salmon Calcitonin and the fall in serum calcium was inversely related to the height of the pre-treatment serum alkaline phosphatase.[19] Woodhouse also found a fall of serum calcium and phosphorus and urinary hydroxyproline in the first hours of treatment.

The serum calcium and phosphorus returned to normal within 24 hours, but urinary hydroxyproline required 4 to 12 months to return to baseline levels.[22]

Palmieri observed a dramatic improvement in the radiologic changes of Paget's disease after 90 days of treatment with synthetic Salmon Calcitonin and parenteral vitamin D.[17] Woodhouse observed no dramatic changes in bone X-rays.[16] Side effects of Calcitonin that have been described include nausea, facial flushing, granular casts in the urine and an increase in the serum parathyroid hormone levels.[12,14,21,22]

Conclusion

In summary, several indications of improvement were present in our patient at the conclusion of Calcitonin therapy. His dyspnea, ankle swelling, cardiomegaly, and pulmonary congestion had all undergone major changes for the better. In addition, a measured drop had occurred in his cardiac output.

Clinical evidence of decreased vascularity existed in that his pulse pressure dropped 30 mm of mercury and the warmth of skin over-lying his right tibia was no longer present. Furthermore, a repeat bone scan was consistent with an altered vascular pattern.

We found that improvements in the radiologic changes of Paget's disease occurred, but were minor. The expected chemical changes took place with treatment. These included a lowered serum calcium, phosphorus, SGOT, LDH, and alkaline phosphatase. Urinary hydroxyproline also dropped. We believe that the lowering of SGOT and LDH levels is probably secondary to improving heart failure.

The unique feature of our patient's clinical course is a measured drop in cardiac output coincident with dissipation of the signs and symptoms of congestive heart failure in a patient whose Paget's disease was treated with Mithramycin and Calcitonin. We suggest that these agents can be an effective form of treatment for heart failure which is caused or aggravated by Paget's disease of bone.

ACKNOWLEDGEMENT

We are indebted to Dr. Omega Silva, Metabolic Section, VA Hospital, Washington, D.C., who made available to us the Salmon Calcitonin used in this study, and to Dr. Ben C. Claunch, section of Nuclear Medicine, VA Hospital, Providence, R.I., for the bone scans.

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Barotrauma of the Inner Ear

Clarence T. Sasaki, M.D., Douglas Bell, M.D. and Paul Levine, M.D.

Abstract—**Difficulty in middle ear autoinflation while diving resulted in rupture of the labyrinthine round and oval windows. Incapacitating vertigo and mild sensory hearing loss became evident five days after injury. The inner ear ruptures were repaired with fat taken from the ear lobe resulting in satisfactory hearing improvement and immediate resolution of vertigo. Recognition of such injury and the necessity for prompt surgical intervention was emphasized.**

Case Report

An experienced scuba diver, a physician, age forty-one years, was diving at a depth of 12 feet in order to retrieve a lost outboard motor. He experienced difficulty with middle ear autoinflation during descent. As autoinflation was accomplished at maximum depth, severe bilateral ear pain resulted, although hearing loss and vertigo were not initial features of his injury. The patient had been troubled with chronic allergic rhinitis for years, and it was his impression that his symptoms were particularly exaggerated this season.

Three days after injury he sought otologic consultation because of "fullness" in both ears. Otoscopic examination revealed bilateral tympanic membrane ecchymoses with left air-fluid level. An audiogram indicated left high frequency sensori-neural loss (Figure 1).

Two days later he was totally incapacitated with obvious right-beating spontaneous nystagmus, nausea, and diaphoresis.

Otoscopy revealed clear resolution of tympanic ecchymosis although the left air-fluid level persisted. On Romberg testing, the patient consistently fell toward the left.

Left transcanal exploratory tympanotomy revealed a brisk perilymph leak from the round window area. The surrounding mucosa was dissected and the defect filled with a fat graft obtained from the left ear lobe. Careful inspection of the stapes footplate showed additional perilymph fistulization from the superior and inferior margins of the annulovestibular joint. Similar repair was accomplished using fat autografting. No injury to the ossicular chain was noted (Figure 2).

On the first postoperative day, vertigo and nystagmus had dramatically resolved. At one month except for minimal occasional unsteadiness, the patient made full recovery with improvement in sensory threshold as well (Figure 1).

Ear	SRT	PB Max	
L	10	90	PRE-OP
L	0	90	POST-OP

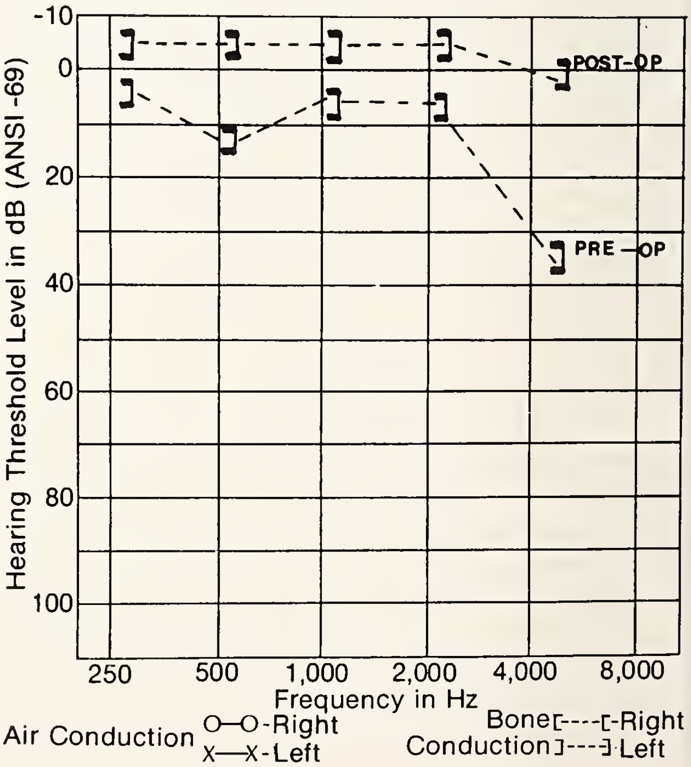

Figure 1
Audiogram showing pre and postoperative bone thresholds, left ear.

DR. CLARENCE T. SASAKI, Assistant Professor of Surgery, and DR. DOUGLAS BELL, Instructor in Surgery, Otolaryngology, both of Yale University School of Medicine. DR. PAUL LEVINE, Assistant Resident in Surgery, Otolaryngology, Yale-New Haven, Hospital.

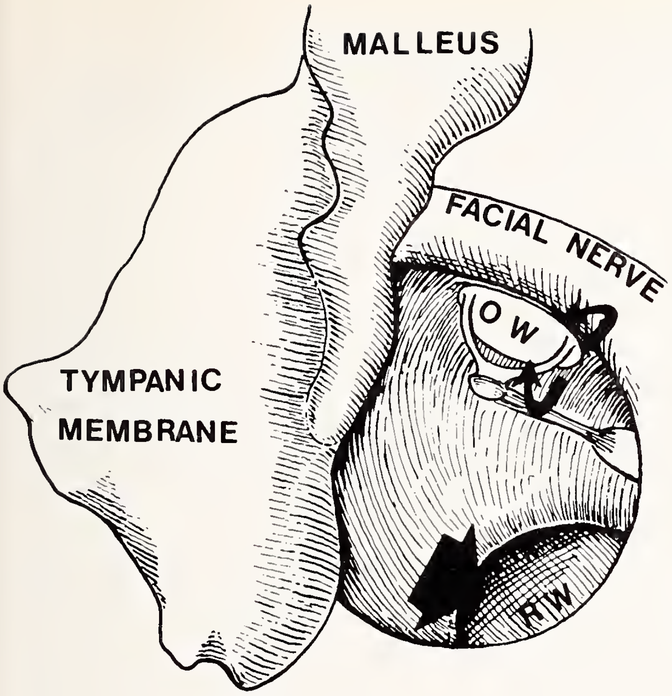

Figure 2
Locations of perilymph fistulae indicated by arrows. O.W.: oval window. R.W.: round window. Incus not shown.

Discussion

Barotrauma to the inner ear had been recognized as a cause of major inner ear injury in divers.[1] Although untreated injuries of this kind frequently resulted in permanent sensori-neural deafness and dizziness, no anatomic description of injury had been available. Freeman et al,[2] however, have recently described round window ruptures in two instances of diving barotrauma. Immediate surgical exploration and repair in their two patients resulted in hearing preservation and/or improvement. The authors cited the common factor in pathogenesis to be concomitant nasal disease and impaired eustachian function. Interestingly, such was the case in our patient as well.

It is our opinion that forceful autoinflation under hyperbaric conditions caused sudden, massive lateral displacement of the tympanic membrane resulting in bottle-cork rupture of the oval window. As inner ear fluids moved toward the oval window, significant displacement of the round window membrane resulted in its rupture as well (Figure 3).

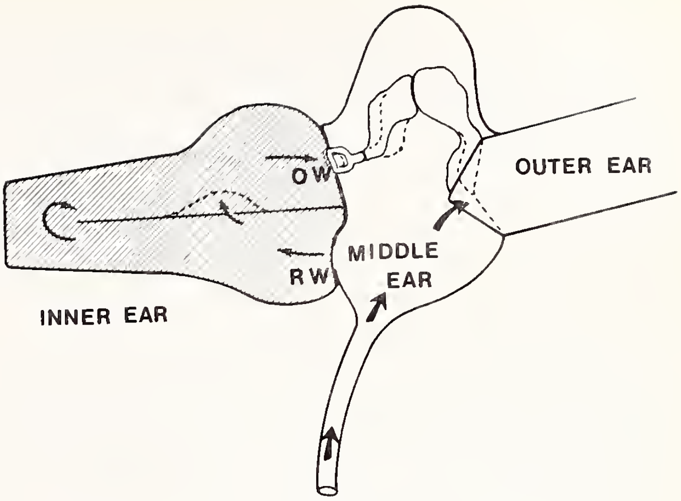

Figure 3
Probable mechanism of injury. Arrows indicate direction of force.

Prompt surgical repair of inner ear fistulae resulted in improved hearing and preservation of vestibular function in our patient.

Summary

Inner ear diving-injury resulting in incapacitating vertigo and mild sensory hearing loss is described. Round and oval window rupture causing massive escape of perilymph is amenable to early surgical repair with preservation of inner ear function.

The importance of avoiding forceful autoinflation under hyperbaric conditions is stressed. In addition, the significance of normal nasal function with regard to ease of autoinflation in divers is emphasized in prevention of inner ear barotrauma.

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Understanding Modern Immunology:
II. The Anatomy and Functions of the Immune System

(Second of Two Parts)

John M. Dwyer, M.D., Ph.D.

The Anatomy of the Immune System

Lymphocytes do not wander aimlessly around the body, they have definite pathways and habitats. "B" lymphocytes tend to cluster in the lymph nodes and spleen. They meet antigen and differentiate to plasma cells in lymphoid tissue. Plasma cells do not circulate in plasma or lymph, their products, antibodies, circulate. Thus, in healthy subjects, B lymphocytes account for 25-35% of the lymphocytes found in peripheral blood. The majority of the lymphocytes found in blood are T lymphocytes. The latter cells also encounter antigen in lymphoid tissue but as these cells themselves mediate their immune functions, they must circulate and pass through vessel walls to antigen containing tissues. In the thoracic duct lymph perhaps 90% or more of the lymphocytes are T lymphocytes.

In the lymph node and spleen the B and T lymphocytes occupy separate and constant anatomical areas. Beneath the capsule of a lymph node in its cortical area, a dense collection of lymphocytes can be seen forming a dark circle that distinguishes the area from the surrounding tissue which contains lymphocytes in a loosely packed stroma. The dense areas are called germinal centers and are the home territory of the B lymphocyte. Figure 1. The germinal centers of a lymph node draining an area of antigenic invasion become very active with much cell division in evidence.

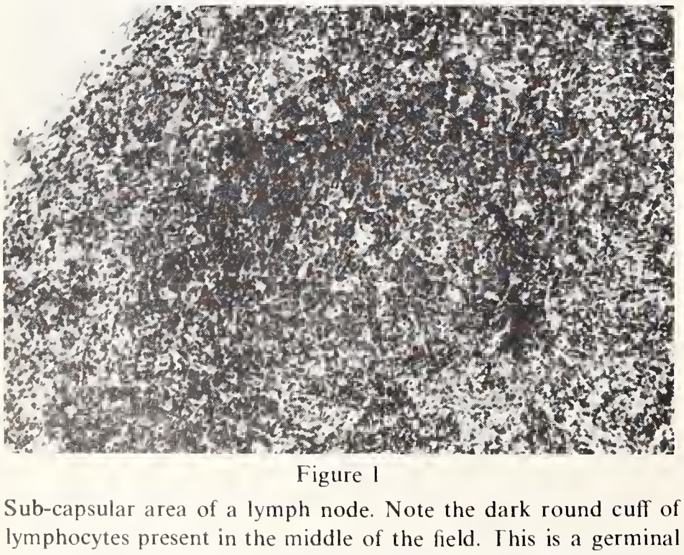

Figure 1

Sub-capsular area of a lymph node. Note the dark round cuff of lymphocytes present in the middle of the field. This is a germinal center, home of the B lymphocyte. In the paracortical area surrounding this area, T cells predominate.

The area surrounding the germinal centers is called the para cortical area and here the T cells congregate. We know little of the mechanisms involved in this type of clonal clustering. Clearly lymphocytes can recognise a given micro-environment and perhaps each other, and their homing characteristics are well defined if little understood. In the spleen, germinal centers cluster around the splenic vein while the T cells are found in the periarticular sheath surrounding the splenic artery (T dependent white pulp). These areas become important in the clinical setting as departures from their normal anatomy may allow the diagnosis of either a primary or secondary immune disorder.

As well as the differences in their circulation pathways, there are numerous functional and biochemical differences between B and T lymphocytes. One of the more important differences concerns the life span of these cells. From animal experiments and much data from human studies it is clear that B cells have a very short half-life; perhaps in the order of eight days while T cells are an extremely long-lived cell.[1] Some T cells may have a half-life of 15-30 years. We know that throughout life the bone marrow is constantly replacing B lymphocytes but there is no evidence for significant T cell production from the mature thymus. In fact, most of the T cells that will serve us throughout life are probably with us shortly after birth. Certainly there is no evidence that thymectomy in childhood or adult life produces a significant fall in T cell numbers or any deficiency in CMI.[2] As T cells perform varied and important functions essential to good health, we need to look after them. The thymus gland becomes less cellular with age and when a patient is stressed, thymic involution seems hastened. There is a considerable body of evidence to suggest that the thymus has endocrine functions and that these may persist in adult life although again no serious sequelae have been noted in this regard following thymectomy. The thymus gland produces an agent called thymosin

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which may play a role in T cell differentiation and/ or the maintenance of a healthy T cell population.[3] This hormone can be found in the blood and is being used in clinical trials on patients with inadequate CMI. Thymectomy may well deprive the individual of this hormone. The other hormonal agent secreted by the thymus, thymin, may play a role in neuromuscular transmission and this fact may explain the common association of thymonas and myasthenia gravis.[4]

Until it is determined conclusively in humans that lost T cells are replaced the bulk of the evidence would suggest that we should regard these cells as precious and minimise their loss. Thus, many clinical procedures including thoracic duct drainage, immunosuppressive therapy and even multiple donations of blood should be re-evaluated in terms of potential T cell loss. The biochemical differences between T and B cells, responsible for much of their functional distinctiveness, is being increasingly recognised. Thus, it is not surprising that drugs may have a selective effect on T or B cells. For example, cyclophosphamide appears to effect B cells more than T cells while the reverse is true with azathioprine.[5] Now that we can type many of the B lymphoid malignancies according to their B or T cell origin (acute lymphatic leukemia is a tumor of T cells, chronic lymphatic leukemia is a tumor of B cells), these selective drug effects are assuming major therapeutic significance.

The Function of T and B Cells

Not surprisingly, these very different types of lymphocytes have very different functions. The major physiological role assigned the B lymphocyte is clearly anti-bacterial. B lymphocyte deficiencies can be equated with recurrent and severe bacterial infection. Most antigens entering the body will provoke a humoral immune response with consequent antibody production but in the maintenance of health, this response is vital only in protecting us from bacteria. Antibodies binding to bacteria may immobilize them or damage them physically but essentially the complex is able to activate phagocytic cells and/ or the complement system to cause an inflammatory response and the destruction and eradication of the organism.

T cell function is much more complex. It is clear that T cell integrity is essential for adequate defenses against viral, fungal, and intracellular bacterial (e.g. nocardia) infection. A child born without a thymus may have little trouble with bacteria but can be killed by measles virus. When a viral or fungal infection occurs, antibodies to these agents are made and these immunoglobulins may help reduce viral replication (measles), but the major and essential thrust is supplied by T cells. Often antibodies are useless (e.g. rubella), and perhaps may even be harmful if they block the T cell response. Such a possibility has been suggested for serum hepatitis.

T cells also play a vital role in preventing the expansion and establishment of malignant cells. Tumor cells have on their surface antigens not present on the surface of the normal cells from which the malignant cell was derived. These tumor specific antigens are recognised by T cells and the malignant cells are destroyed. Decreased T cell efficiency is associated with a much increased risk of malignancy developing. Similarly, T cells recognise foreign histocompatibility antigens and reject grafted tissues.

T cells can easily be distinguished from B cells as the former bind sheep red blood cells to their surface forming "rosettes," B cells cannot do this. Figure 2.

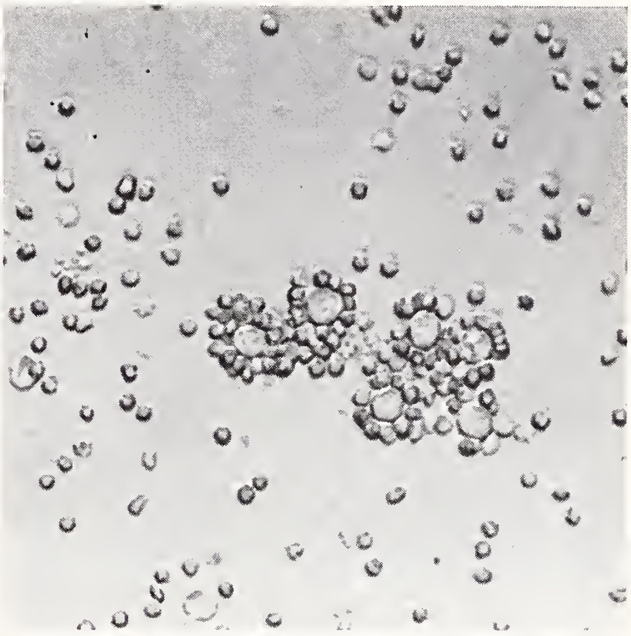

Figure 2

Human peripheral blood T lymphocytes binding sheep red blood cells to their surface to form rosettes.

While it is proper to concentrate on the differences between T and B cells, it is important to realize that the phytogenetically older T cell system can collaborate with and modify B cell responses. Thus it appears that for most antigens the production of optimal amounts of high affinity IgG antibody requires T cell collaboration with B cells. The nature of the collaboration is understood only in general terms but it seems likely that a T cell product or surface structure is able to bind to an antigen in some way altering the presentation of the antigen to the B cell with optimal IgG production ensuing. We have already discussed the importance of this concept in understanding auto-immune disease. The remaining major T cell function involves the control of the immune response. Such a powerful biological response must be actively controlled to prevent excesses that would do more harm than good. For example, a set time sequence seems associated with intradermal delayed hypersensitivity responses. In man these responses reach a peak at 48 hours and rapidly wane after 72 hours despite the continuing presence of substantial amounts of antigen. Evidence has been forwarded that strongly suggests that either a sub-population of T cells or T cells at a stage of their response can actively suppress immune responses. These suppressor T cells can control B cell responses as well as T cell responses. Once familiar with the facts outlined above it is easy to grasp and even anticipate many of the important facts surrounding immunological disease. Thus, the concept that viruses or drugs may break T cell tolerance to self-tissues resulting in increased autoantibody production is understandable in terms of T-B cell collaboration. The increased incidence of malignancy in kidney homograft recipients treated with the T cell suppressant, azathioprine, is not surprising. Again, the logical approach of the current trends in immunotherapy directed at reducing the levels of blocking antibody directed against tumor antigens and increasing T cell reactivity against these same antigens becomes apparent.

Clinical immunology is entering an intensely practical period. At both the preventative and therapeutic level dividends are available and increasing thanks to an intense and expensive investment in researching immunological mechanisms. Understanding of these mechanisms by physicians will ensure that the profits are spread equally among those people whose T and B lymphocytes could do with a little help.

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AMA to Support Survey of Antibiotic Usage Patterns

A pilot study to analyze the antibiotic usage patterns of a cross section of American physicians will be conducted by the American Medical Association.

The $70,000 study will be done under the direction of the AMA's Committee on Antibiotic Utilization and will be funded by the AMA Education and Research Foundation.

The proposed study, committee officials said, will be the first relatively large-scale effort to study the use of antibiotics in outpatients and to include detailed diagnostic information.

The committee's proposal said the study will be done in cooperation with the Kaiser-Permanente Medical Group, the San Joaquin Foundation, and the University of Southern California-Los Angeles County Hospital, all in California.

In approving funding, AMA-ERF's directors asked the committee to include in its study a fee-for-service ambulatory group.

The project coordinator will be Joseph F. Sadusk Jr., M.D., a member of the committee on antibiotic utilization, former director of the Food and Drug Administration's Department of Medicine and formerly senior vice president of Warner-Lambert Co.

The committee told AMA-ERF's directors that the ad hoc group's deliberations have centered on how to investigate objectively the patterns of antibiotic utilization in the U.S., particularly in the outpatient setting. The committee said it has found that much good data on an antibiotic usage already exist in computer banks of university hospitals and medical foundations.

"If accumulated and correlated," the committee said, "these data will yield valuable information that can serve as a base for establishing usage guidelines. It is (our) belief that guidelines predicated on such data have an infinitely better chance of influencing the prescribing habits of the medical practitioner than guidelines based only upon a consensus opinion, regardless of how well it might be formulated."

The pilot study will cover only patients receiving ambulatory care and will be a retrospective study. The committee hopes the pilot study will lead to a large-scale prospective study.

Members of the AMA's Ad Hoc Committee on Antibiotic Utilization, in addition to Dr. Sadusk, are M.D.s Morton D. Bogdonoff, head of the Department of Medicine, the Abraham Lincoln School of Medicine, Chicago; Maxwell Finland, professor emeritus, Channing Laboratory, Harvard University and Boston City Hospital, Boston; John E. Kasik, professor of medicine, Oakdale Hospital Chest Unit, University of Iowa, Oakdale, Iowa; William H. Morris Jr., Dept. of Pediatrics, the Hammond Clinic, Munster, Indiana.

Perinatal Morbidity and Mortality Committee

Case History and Commentary

William E. Lattanzi, M.D., *Chairman*

Introduction

This is the fourth in a series of perinatal case presentations and commentary submitted by the Connecticut State Medical Society's Committee to Study Perinatal Morbidity and Mortality.

This case material will be actual patients delivered in the State that are felt by the Committee to represent preventable or probably preventable deaths. The case selected will be discussed by either members of the Committee or an invited guest.

The purpose of the presentation and commentary will be the dissemination of instructional information to the readers of the Journal.

This month's discussant is Dr. Howard Pearson, Professor and Chairman of the Department of Pediatrics at Yale.

Case History

Five years prior to her first pregnancy the patient was in the hospital for a thyroidectomy at which time she received one unit of O Rh+ blood. Her first pregnancy occurred and she was found to be type O Rh negative. Ant. Rh were as follows: 18 weeks-negative; 30 weeks-negative; 34 weeks-positive (titer unknown); 35 weeks-positive 1 to 8; 36 weeks-positive 1 to 2. At 37 weeks attempted induction failed and an amniocentesis was attempted and failed. At 38 weeks a cesarean section was done after another failed induction and the baby was found to be Rh+, Coombs positive and was treated with phototherapy without incident.

Her second pregnancy occurred three years later and at 12 weeks the maternal titer was 1 to 32. At 22 weeks an amniocentesis was done with an optical density of 0.105. At 24 weeks amniocentesis revealed .05 OD, at 26 weeks .05 OD. 30 weeks .03 OD, and at 34 weeks an OD of .03. (Figure 1) Lecithin was equal to sphingomyelin. A repeat section was advised for 37 weeks with the thought that the baby was probably Rh negative. At 36 weeks another amniocentesis revealed an optical density 0.16 with L greater than S. The baby was then delivered.

The baby weighed 5 lbs. 8 ozs., was severely hydropic and in spite of immediate exchange transfusion, died at 24 hours of life.

Discussion

Spectrophotometric analysis of bilirubin in amniotic fluid has become an established technique for managing pregnancies of sensitized Rh negative women. The data obtained from these analyses have provided important information in decisions concerning early induction of labor or the need for intrauterine transfusion to prevent stillbirth from fetal hydrops. The O.D. 450 mu (Liley value) of amniotic fluid as a measurement of bilirubin has been shown to correlate quite closely with the severity of fetal hemolysis. However, from time to time this determination has been inaccurate in prognosis.[1] [2] Low values have been observed in pregnancies involving severely affected infants; conversely, high levels have been documented when minimal or no fetal hemolytic disease was present. The frequency of false negative results is quite low. Muller-Eberhard and others noted only one instance out of 39 cases in which a gross clinical error was made on the basis of serial Liley values.[3]

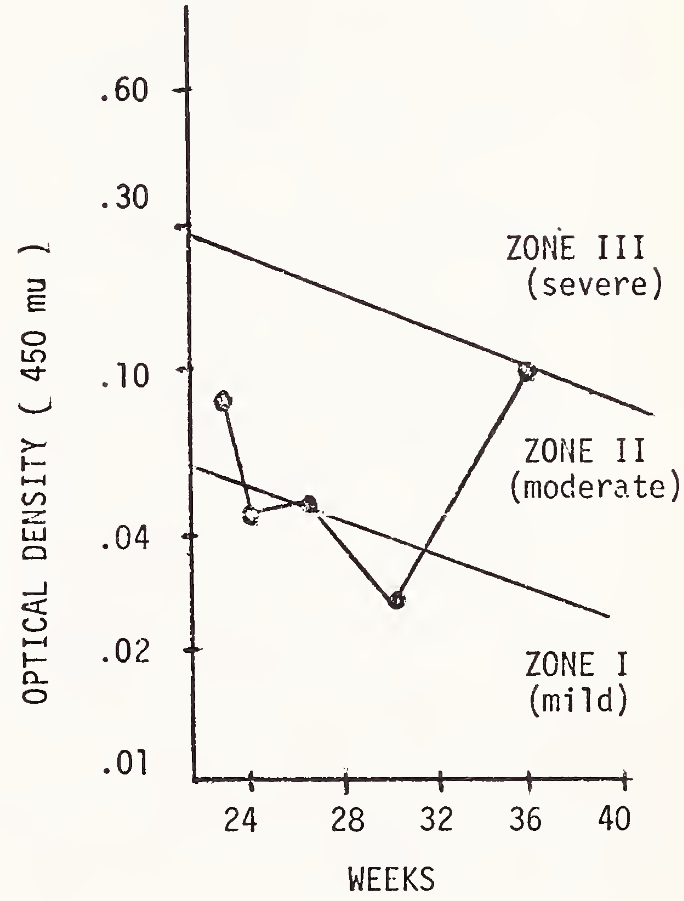

Figure 1

The case presented here represents an apparent failure of amniotic fluid analysis to predict severe fetal disease. A gravida II Rh negative woman, who had been maximally sensitized by a transfusion of Rh positive blood, had four amniocenteses. At 22 weeks, the O.D. 450 mu was .105, a value falling in mid-Zone II, as described by Liley. This finding was consistent with moderate hemolytic disease.

DR. WILLIAM E. LATTANZI, Chairman, Connecticut State Medical Society's Committee to Study Perinatal Morbidity and Mortality.

Quite properly, amniocentesis was repeated at 24 weeks. The O.D. 450 mu was found to be .05, which falls only in high Zone I. The low and falling O.D. was considered to indicate mild or no hemolytic disease. Repeat analyses at 26 and 30 weeks confirmed the low O.D. supporting this optimistic prognosis. A final amniocentesis done at 36 weeks surprisingly revealed a precipitious increase in the O.D. 450 mu to .16, which is high in Zone II and suggestive of moderately severe hemolytic disease. At this point, immediate delivery was effected. The severely hydropic baby died despite exchange transfusion therapy.

A certain explanation for these confusing and contradictory findings cannot be advanced; however, the occasional apparent failure of amniotic fluid spectral assay to predict severe fetal disease (false negative result) has been recognized for more than a decade. Spectrophotometric analysis may be invalid if the amniotic fluid is contaminated by maternal or fetal blood or meconium. In addition, since bilirubin is photosensitive, the amniotic fluid specimen must be protected from the light to avoid a falsely low O.D. 450 mu. Most laboratories recognize these possible technical sources of error and take precautions to avoid them. Since there were three consecutively low O.D. 450 mu values in the present case, technical reasons for error seem unlikely. Another possible source of "false negative" result can be polyhydramnios, since an increased volume of amniotic fluid may dilute the bilirubin resulting in a spuriously low Liley value. In most instances no explanation can be advanced for disparate results.

In an attempt to avoid the occasional prognostic errors, some investigators have employed more extensive and detailed assays. Muller-Eberhard has shown that the ratio of chemical bilirubin to albumin concentrations (Bil:Alb) and the ratio of hemopexin to albumin (Hx:Alb) in amniotic fluid provide a more reliable prediction of fetal outcome than the Liley value. Both false negative and false positive results which occurred using the O.D. 450 mu were corrected when these ratios were employed.

As this case demonstrates, physicians managing Rh sensitized women should recognize that, as ordinarily performed, amniotic fluid analysis is quite good, but not absolutely invariable, diagnostic test. The results should be evaluated in conjunction with the history and other clinical features. The extreme type of immunization by transfusion that this mother experienced should have made the physician very wary. RBC genotyping of the father to assess whether or not this child *could* be Rh negative might also have been helpful in the management of this case.

If other studies corroborate the much greater reliability of pigment/protein ratios, these determinations may become more widely used. As Rh sensitization becomes more and more unusual, a more compelling case can be made for designation of regional centers for management of Rh sensitized women. Only where there are adequate numbers of cases can laboratory investment, capability and reliability be assured.

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Surgery Statistics

The highest proportions of the estimated 11 million patients treated surgically in the United States in 1968 were discharged from hospitals in the northeast and west regions of the country. In a report entitled "Surgical Operations in Short-Stay Hospitals," the U.S. Department of Health, Education, and Welfare also noted that adult patients accounted for 84 percent of the operations and procedures performed. The most frequently reported surgical operation, for patients of all ages, was tonsillectomy with or without adenoidectomy. Next, in order of performance, were repair of inguinal hernia and hysterectomy.

The President's Page

As my term of office draws to a close, I think I can see certain trends which will be brought about inevitably in the future of American society. The first and most obvious is change marked by acceleration, diversity and transience. The voting population is becoming more interested in dealing directly with its own problems in every aspect. This includes medicine. This voting population, of which physicians are only a small part, elects the legislative body and the leaders of the executive branch. The results and changes which come out of these bodies are not only the responsibility of the bodies themselves but are the basic responsibility of those who vote. In other words, the people will have their way whether their way is right or wrong, whether their way reflects wisdom or misunderstanding.

We have behind us the experiences of other countries whose governments have elected to take over medicine. Hopefully we can learn from the mistakes that were made in these processes. We should know that to bellow and roar and beat our heads to a bloody pulp against change of any sort is as fruitless as it is stupid. We should know by now that it is impossible to keep government out of medicine entirely because the people want certain things that they have not gotten from medicine as it exists today.

What our problem is is to know how to act and react in order to preserve and improve the quality of medicine as it exists today, and at the same time give people the availability of medical care and the education for health to know what to ask of the medical profession. We must accept the demand of the public that our laundry be clean, but we must insist that we do this ourselves because we are the only ones capable of doing it and at the same time maintaining and improving the quality of medical care. Where cutting the cost is possible without interfering with the quality, we should cut costs. Where increasing costs improves the quality, we should increase costs.

Above all, we should insist that the quality of medical care be the responsibility of physicians and that a reasonable standard of living be provided to us in keeping with our education and ability to deliver quality care.

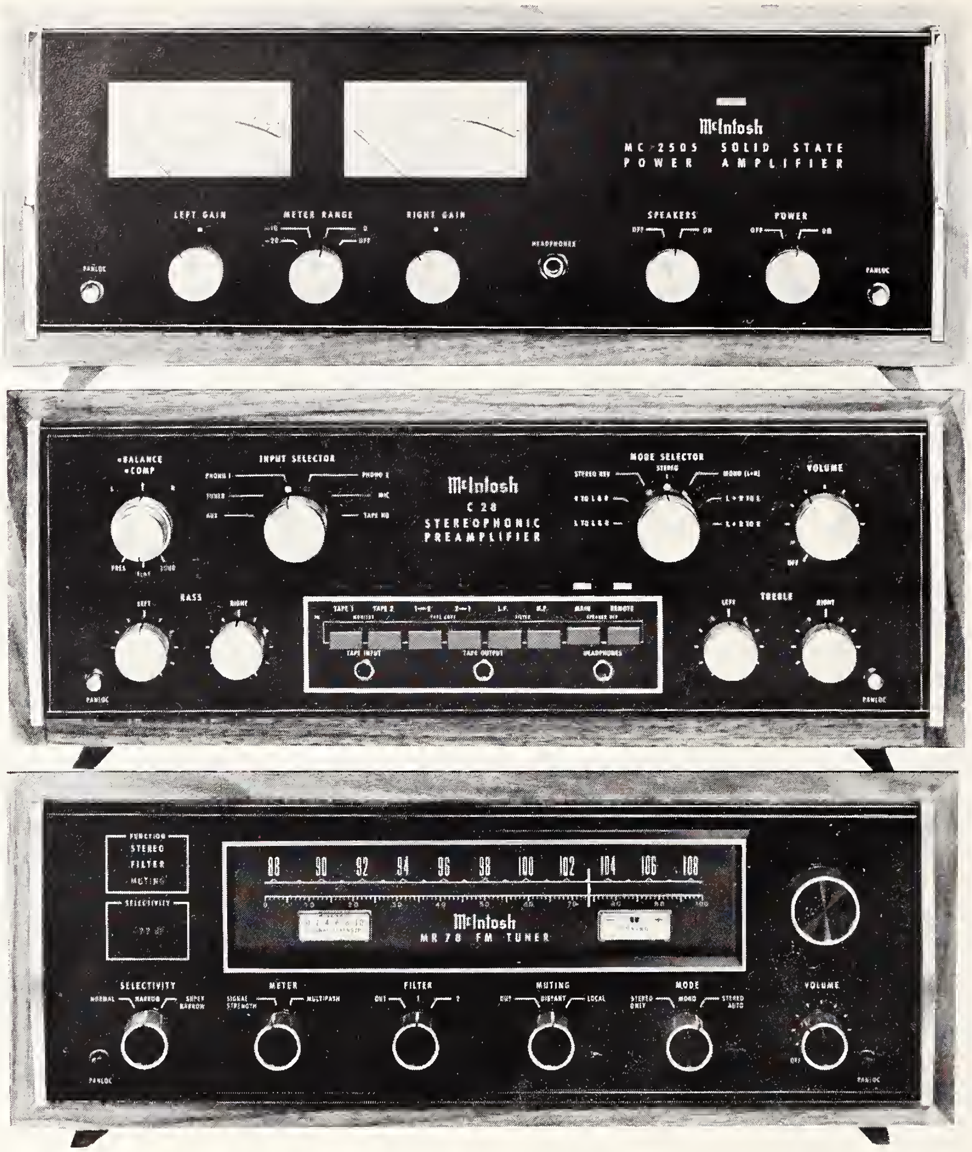
We have to ride with certain punches such as Medicare, Medicaid, PSRO and impending national health legislation. We must recognise the need for certain things like catastrophic health insurance. But in order to maintain the expected quality of care we must have input into both the laws and the regulations that come out of the bureaucracies that are built to carry out the laws. We can warn and fight against the costs that accompany the build-up of these bureaucracies such as we did during the impending days of Medicare, but if we lose, we must still do the best we can to keep the quality high under the law, otherwise, the quality will be torn out of our hands by uninformed legislatures, bureaucracies and public. To bury our heads in the sand means to bury quality as well. To show a willingness to cooperate with the law gives us an outside chance at least to maintain quality and to establish more input into future laws and regulations. In this way we may be able to avoid some of the mistakes committed by other countries before us. We even may be able to hold down the build-up of some of these catastrophically expensive bureaucracies as well. But we must do it through wisdom and statesmanship rather than through emotional and rhetorical temper tantrums.

This does not mean that we fight any the less for quality. It simply means that we fight with our heads rather than our emotions to keep the control of those things which are sacred to us in the medical profession.

During the last year we have taken strides in this direction through the AMA and the Connecticut State Medical Society. I'm sure that we will continue to do so.

James H. Root, Jr., M.D.
President

In A Field Crowded With Talented Amateurs . . .



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Reflections From The Dean's Office

Robert U. Massey, M.D.

In the recent jockeying for position among the health planners following the passage of the National Health Planning Act (PL93-641), it became evident again how terribly complex our civilization has grown.

Masanao Toda, Professor of Psychology at Hakkaido University in Japan, has written: "As there seems to be no built-in stopping mechanism in the program that makes man work this way, we now arrive at the not-yet famous second law of civilization dynamics: *in an isolated human system the negative entropy it contains has a tendency to increase.* God knows what the first law is."[1]

Dr. Toda has urged that we work to develop a science of civilization recognizing that it will not be a science built on controlled experimental data. Only the masses of material available from historic documents will provide the base for forming hypotheses. There are problems here which he recognizes. The observers have been looking at it from the inside and at very close range; the mass of data is huge and the quality of the observations variable. In spite of this he asserts that a science of civilization is both possible and necessary if we are to have any say about our future.

Those of us in medicine have a large part to play both in this act and in the acts to follow. Measured in terms of the gross national product in developed nations, health services and goods account for nearly 10 percent, and may be more if we include everything that bears on health.

The desire to plan so large an enterprise, to make it everywhere equally effective, to incorporate all the knowledge about human biology, and to apply rationally all the most recent technologies, to answer all the needs and to do so with wisdom, competence, and compassion is well nigh irresistible. To design and carry out any such plan would be unaffordable because in this market the demand always outstrips the supply.

Sooner or later, as Toda suggests, a civilization runs out of energy, the second law of thermodynamics inevitably takes over from the second law of civilization, and the whole thing runs down. The assumption is that if we had a science of civilization we would know enough to keep this accelerating rate of growth and complexity and subsequent decline from happening.

We probably cannot wait that long; and, I suspect, this wait would be in vain. While the quest should not be abandoned, a science of civilization may not be possible. A clinical approach instead may be called for—making decisions on insufficient and often inaccurate data. The needs for health services are known and can be described, especially if we do not waste too much time debating the differences between needs, wants, and demands. We should know by now what medicine can and cannot do, although we often deceive ourselves about that. We know within limits what is affordable. That should be enough to enable us to move to a working diagnosis, and, because the risks are high, to institute therapy.

Therapy is not another conference. It is action—disciplined, controlled, sometimes tentative—but action none the less. The time for meetings without issue is over. The patient demands to have his problems attended to.

In the past ten or fifteen years in which I have observed and been caught up in the continuing round of health planning efforts, conflicting legislation, and incomprehensible guidelines, it has been difficult for me to recognize any signs that the nation's health has been improving, or even that the process of providing health services has been more effective as a result. Negative assertions of this kind, of course, are unprovable. The frenetic activities of the past decade were historically determined and were a necessary prelude.

Nevertheless, now that we have talked it all over and ordered all the tests that we need, we should go to the chart and write the orders. Or to stay with my earlier metaphor, I believe we are ready for the next act.

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ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut School of Medicine, Farmington.

"For when was honey ever made with one bee in the hive"...

Thomas Hood, *The Last Man*

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Connecticut Medicine

Editorials

Human Inhumanity

This nation's generosity has been among the brightest pages in human history and yet no form of human crime against humans is unknown to us, both as sins of commission and omission. Our neglect of the mentally ill and the mentally unfit or subnormal is possibly the most widespread abuse through non-action on the part of those who could and should act. Again and again and again different "treatment" programs have been advocated to remedy the abuses in and by extant institutions, usually with the promise that the new measures would also be more "economic." More economic for whom?

The chronic mentally ill represent the poorest of the poor in our society, and now they have been consigned geographically to the poorest areas of society—the inner city. Thanks to effective medication during the past two decades and the impetus of the Mental Health Act of 1963 the census in our large under-staffed mental hospitals has been halved or reduced even below 50% of bed capacity—a fine achievement in logistics. Some of these patients have, indeed, been rehabilitated and have re-entered society successfully even after years of institutionalized neglect. Many of them, however, have been only moved to inadequate nursing homes, to single rooms in dilapidated hotels and boarding houses and occasionally to their families, regardless of potential stress and burden on such families. Mostly well-behaved and docile, often due to chemotherapy whose long-range effects we are just beginning to discover, these patients are indeed in the community, but hardly part of it. Like the poor who are not mentally ill, the discharged patients are unable to cope effectively because they lack instrumental and social skills, and the capacity to act independently in their own behalf.

Refusal to acknowledge that a sector of our and any other population must necessarily be at the lower end of the psychosocial ability and adequacy spectrum prevents humane treatment and provisions to meet the dependency needs of the dependent. Now, besides economic arguments and public and professional dissatisfaction with the large, warehouse-like mental hospitals, some legalistic civil-liberty-eager-beavers have also converged to create an anti-hospital atmosphere which is counter-therapeutic. However, it is our penny-wise-pound-foolish shortsightedness as well as our misguided societal priorities that prevent the appropriation of sufficient funds to treat those mentally ill who could be helped in professionally staffed, humane institutions, and to treat them long enough, even though not all of them can be rehabilitated in spite of our best efforts. But, we could at least provide decent living conditions for the latter cohorts.

Much chronic disability could be prevented in active treatment settings preferably in the community, but not only on seven- or twenty-one day units. These are arbitrary time limits not based on clinical experience although some patients need spend only days and not weeks or months in the hospital. But insurance companies and governments are eager to buy the slogans for more humane treatment and "less involuntary incarceration" if they also save money. Therefore, brief symptomatic treatment is allegedly better than long intensive therapy; outpatient status is preferred to hospitalization and three weeks' hospitalization is "preferable" to three years' institutional care. But institutional care need not be hospital care, but could be humane residential and work communities for those who cannot lead an unsheltered existence.

Of course, all this is better for the better patient. A biopsy is better than a mastectomy if you have a benign lesion, but would be bad, albeit cheap treatment for cancer. Psychosis is rarely benign, and in terms of effective treatment psychotic patients may fare no better or worse than patients with leukemia, except that they live longer. Are cancer patients entitled to more consideration than schizophrenic persons? Cancer is a fatal disease for many, affecting mostly older prople, but nobody would advocate giving up on treating them as long as there is hope for life. Schizophrenia involves the young and most victims live on and die with it, but not usually because of it. Many more would not have to live crippled by it if treated early and intensively and for as long as there is some hope for improvement. Most recover from their first break, only to be left to their own resources which are usually inadequate for social participation, and as failure after failure confronts them they retreat further and further into their psychotic existence whether in custodial-care-giving hospitals or in "the community." Both are pseudonyms for giving inadequate treatment.

The blurring of science and politics is a particular hazard and burden for the mental health field. It has been more dependent on public resources than other areas of medical and social endeavor because of the pervasive ambivalence which attaches to—indeed is inherent in—questioning anybody's sanity or humanness. This ambivalence operates no matter whether the quest for resources concerns study and research, or treatment.

As the government may soon enter the general health insurance field, we must guard against acting out our ambivalence by opposing the extension of health care and treatment to all, because good care does cost more money, i.e., more taxes, than bad care or neglect. The record of government-financed medicine is mostly disgraceful in the mental health field and often less than adequate in the United States Veterans Administration. But we must not use the government as the scapegoat to hide our ambivalence towards those who cannot cope, our collective sins of omission to pay through taxes or in some way the cost for optimal and humane treatment and care for the acute and the chronic mentally disturbed.

STEPHEN FLECK, M.D.

The Malpractice Mess

Perhaps reluctantly, this profession must come to the realization that professional liability insurance is falling far short of its goals and a new concept is required. Primarily, medical malpractice failed because we doctors have not told our patients that they are entering a high risk industry and that there are certain untoward results which, whether they are due to negligence or unfortunate circumstances, are compensable.

It is completely impossible for a physician or surgeon to go over all the possible dangers and untoward results inherent in the use of any drug or operative procedure. Even if the physician did detail all these possible dangers, he has no guarantee that the patient will remember all information given him for informed consent after the fact. As far as patients are concerned, their compensation is miserly. Less than twenty-five percent of the premium dollar filters down to the patient as payment for untoward results. Costly court trials consume too much time and too much money and in the end detract from the patient's just compensation.

The patient must be compensated for injury, and this should be made known to him prior to his contract with the physician or surgeon. Only those injuries listed on a manifest-agreement should be compensable, and no others. The amounts of compensation should be stated prior to the patient's entrance into a patient-doctor relationship, and there should be little or no appeal. We therefore must have a medical compensation commission in this state, with a panel made up of senior experienced practitioners, including three physicians and three lawyers. They shall determine whether the injury was a direct result of medical practice and recommend whether the case be dropped or compensated. Payment must be made directly to the patient in the full amount that he agreed to at the time he entered into contract with his physician or surgeon. The court costs, contingency fees, and long drawn out legal contention must be a thing of the past. If the patient is hurt, he must be compensated, and this must be done as justly, as fairly as possible, and as soon as possible. Professional liability insurance coverage has been a failure and is becoming an expensive and intolerable burden to the practitioner, and indirectly to the patient consumer. It must be replaced by a new approach and it appears that a medical compensation commission seems the only fair way to do this.

G. S. PARRELLA, M.D.

Letters To The Editor

Letters to the Editor are welcomed and will be published, if found suitable, as space permits. Like other material submitted for publication, they must be typewritten *double spaced* (including references), must not exceed 1-1/2 pages in length and will be subject to editing and possible abridgment.

THE URGENT NEED FOR CADAVER KIDNEYS

To the Editor: More than sixty patients in Connecticut are waiting for a suitable cadaver kidney transplant so that they may have a chance to be cured from endstage renal disease. Many have been waiting for more than a year, at a cost of about $20,000 annually per patient when maintained at a center dialysis facility. The number of cadaver kidneys procured in Connecticut is below the national average for areas with active transplant centers.

The problem of inadequate numbers of transplantable cadaver kidneys is not due to an absolute low number of cadavers, but rather to the failure of making cadaver kidneys available for transplantation. There were 162 highway deaths in Connecticut during the first six months of 1974. Approximately 70% of highway fatalities are due to head injury and thus are potentially suitable kidney donors. If only 25% of those victims had been able to reach a hospital before death, 52 cadaver kidneys would have been available for transplantation, a sufficient number to take care of almost all of the potential recipients in the entire state of Connecticut. However, in the half of the state covered by the Hartford Hospital Transplantation Service, only five cadavers underwent donor nephrectomy in that period.

In general, donors suitable to have kidneys removed for transplantation are patients with irreversible brain damage, who have good renal function, with respiration being supported entirely by a mechanical respirator. The ages may range from one to 45 years. Excluded are patients having a history of hypertension, malignant disease (other than primary to the brain), the presence of a systemic infectious disease, or longstanding diabetes mellitus. Permission must be obtained from the next of kin and from the medical examiner in cases under his jurisdiction.

There are other causes of death which permit the salvage of kidneys suitable for transplantation. Resuscitation following a cardiac arrest from a variety of causes occasionally results in irreversible brain damage. Congenital vascular malformation of the brain may cause irreversible brain damage.

Physicians with suitable donors or seeking additional information should contact the Hartford Hospital Transplantation Service, for northeast Connecticut (Robert Schweizer, M.D., 549-5897), or the Yale Transplantation Service, for southwest Connecticut (Bernard Lytton, M.D. and Martin Schiff, M.D., 436-1573).

The patients waiting for kidney transplants in the state of Connecticut urgently need your help.

Robert T. Schweizer, M.D.

Department of Surgery
Hartford Hospital

DISTRIBUTION OF PHYSICIANS IN CONNECTICUT

To the Editor: It is obvious to anyone residing or practicing in Newington that this town does not have anything like the 41 physicians listed in Table 1 on Page 44 of the January 1975 issue of *Connecticut Medicine.*

A brief look at the local telephone books reveals only 14 physicians with Newington telephone numbers. Four of these are part time obstetricians. An additional four are located at the Newington Children's Hospital and include the Executive and Medical Director and three pediatric subspecialists who are available mainly on a referral basis. The remaining six physicians include one part time internist, 2 full time internists (one of whom died recently), one family practitioner, one pediatrician, and one general surgeon.

If one accepts the number of physicians in Newington as 14 regardless of the extent of their availability, then where are the other 27 physicians?

I suspect that these are other employees and house staff of the Children's Hospital and of the Veteran's Administration Hospital and Cedarcrest Hospital which are all located in Newington. Many of these physicians list Newington as their town of practice in the licensure process yet they are not available for medical care to the residents of this town.

Before this article on the distribution of physicians in Connecticut becomes accepted for planning purposes, I would suggest that the numbers of physicians listed for each town be rechecked to avoid the marked error that has occurred with regard to Newington's physicians.

Herman Wolfson, M.D.

Newington, CT.

The above letter was referred to the authors of the article in question who offer the following reply:

To the Editor: The data on physician distribution presented in the January, 1975 issue of *Connecticut Medicine* reflects numbers of active physicians on official state licensure records as explained in "The Data" section of the article. The 41 names attached to the number of physicians indicated for Newington may be found in the State Health Department publication *List of Physicians,* 1973, page 29. As might be expected, a number of these have institutional addresses and therefore probably do not appear in the telephone directory for Newington.

Licensure data, at this time, represents the best standardized information available for making comparisons between different areas in the state and the only data which could practically be utilized for designation of shortage areas for the Department of Health, Education, and Welfare. A great deal of work, time, and money is required to obtain and organize data with detail beyond that which can be derived from licensure records.

The limitations of licensure data were recognized in the "Conclusion" section of the January article and mention was made of efforts currently in progress to overcome these data limitations at least for the Primary Care (general practice, internist, pediatrician, obstetrics/gynecology) segment of Connecticut's physicians. The primary care study briefly mentioned in the January article has involved as one component the mailing of questionnaires to all primary care physicians in the state. Information requested included items which will allow an analysis by town of time actually spent in direct primary care in private offices, clinics, etc., patients seen per hour, age of physician, type of practice, and a great deal of additional information to better specify existing availability of physicians which can then be related to need or shortage criteria, population demand characteristics, and to make educated projections of probable future situations.

A great deal more could be said about the data collection and analysis component as well as the other components of the Primary Care Task Force study but the major point of this reply is that we are aware of the limitations of the physician data in the January article and of the limitations in data related to other areas of health care. As indicated, this awareness has been translated into an extensive study which has had responses from 75% of the primary care physicians in the state. Hopefully this more reliable information concerning physician distribution will be published within the next six months.

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Connecticut State Medical Society members are invited to write to the Editor expressing their opinions or giving information on matters of mutual interest. The Editorial Committee reserves the right to select or reject communications. As with other material, all correspondence will be subject to the usual editing and possible abridgment. Letters to the Editor should be typed double-spaced (including references) with conventional margins. The length of the text is limited to 1½ manuscript pages. Address: J. Alfred Fabro, Editor, CONNECTICUT MEDICINE, 160 St. Ronan Street, New Haven, CT 06511.

Psychosurgery: Perspective on a Current Issue

Bertram S. Brown, M.D., Louis A. Wienckowski, Ph.D., and Lyle W. Bivens, Ph.D.

The control of human behavior has become an issue of considerable concern and prominence. Most of the concern is generated by a rapidly advancing biomedical and behavioral science technology that provides explicit and powerful means for controlling behavior, and thus carries with it a correspondingly increased potential for abuse. Much recent publicity has focused on the control of behavior by removing or destroying portions of the human brain, a procedure usually called psychosurgery. It also is called psychiatric surgery or functional neurosurgery. Psychosurgery is not a new technology. It has been used for nearly forty years to treat a variety of mental illnesses. But the dramatic and drastic nature of psychosurgery has aroused many concerns about its potential abuse. The following discussion is intended to provide an objective account of some of these concerns as well as to offset some of the misconceptions that have been fostered by recent and strongly critical publicity.

What is Psychosurgery?

Psychosurgery can be defined as surgical removal or destruction of brain tissue or the cutting of brain tissue to disconnect one part of the brain from another with the *intent of altering behavior*. Usually it is performed in the absence of direct evidence of existing structural disease or damage in the brain.

The surgical treatment of epilepsy, while in one sense a form of psychosurgery since behavioral symptoms are altered, should be excluded from this discussion when the disease can be clearly diagnosed and there is convincing evidence that epilepsy is caused by organic pathology in the brain. Of course any other neurosurgical treatment to repair or remove damaged brain tissue, or to remove tumors, is not psychosurgery.

Ever since the first "radical" lobotomies were performed, in which virtually all of the subcortical connections of the frontal lobe were severed, surgeons have attempted to refine the techniques to limit the brain destruction in the hope of reducing adverse side-effects.

This search for limitation of destruction of brain tissue (and presumably of adverse side-effects) culminated in stereotaxic techniques in which a small electrode is positioned in the brain. Geometric coordinates and X-ray inspection are used to place the electrode in a precise location and then the tissue is destroyed at the electrode tip by passing a current through the electrode. With the development of stereotaxic techniques, structures deep within the brain became accessible for destruction, and amygdalotomy, thalamotomy, and hypothalamotomy began to replace lobotomy as psychosurgical procedures.

Psychosurgery was recommended for curing or ameliorating schizophrenia, depression, homosexuality, childhood behavior disorders, criminal behavior and a variety of narcotic addiction and other psychiatric problems. For a period from about 1936 to 1955 lobotomy was enthusiastically embraced by a large number of medical and psychiatric practitioners in this country and in England. The greatest proportion of psychosurgical treatments was upon schizophrenic patients, who were often difficult to manage and totally disabled in terms of functioning in society. A large number of psychosurgical procedures were performed in the United States (perhaps as many as 50,000 between 1936 and the mid-1950's). These operations were especially popular in England, and as late as 1962 an English study estimated that between 400 and 525 operations a year were being performed there.

Evaluations of Psychosurgery

Starting with the first lobotomy by Egas Moniz in Portugal in 1935, there was considerable criticism of the technique and of the exaggerated claims by its proponents of the curative power of lobotomy.

In 1947, an exhaustive study of 48 mental patients, 24 of whom had undergone some form of psychosurgery (lobotomy or topectomy) was undertaken by a group of scientists called the Columbia-Greystone Associates. Neither the original nor a follow-up study 3½ years later, was able to provide any substantial scientific evidence that these psychosurgical procedures were useful.

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Many smaller studies, using small numbers of patients with varied psychiatric or behavioral disorders, have been reported in the literature. Surgical techniques range from lobotomies to the implantation of radioactive pellets to destroy deep brain tissue. Although many of the published studies are deficient in methodology and clinical reporting, there are several that conclude that psychosurgery can be useful in selected cases as a "last resort treatment." One study goes so far as to suggest that leucotomy may be the "treatment of choice" in certain cases, rather than being used as a last resort.

In fact, lobotomy had a clear, albeit limited, usefulness. Lobotomy was a "therapy of desperation," but it frequently improved the functioning of patients suffering from severe mental illness, either by improving their condition within the hospital or by permitting them to lead useful lives outside the hospital. The popular conception that lobotomy turns a person into a "vegetable" is not true. Many of the psychological changes produced by lobotomy are often much more subtle than is popularly believed. Faced with the choice of leaving a patient raving in the back ward of a mental hospital, soiling himself with his own feces, and attacking other patients and staff, or performing a lobotomy with a reasonably good chance of improving his condition so he can be moved to a ward with better conditions, many reasonable people would make the latter choice. Although in many cases lobotomized patients who were able to be discharged from the hospital functioned at a lower intellectual level than prior to the onset of their mental illness, this was better than the realistic and grim prospect of spending the rest of their lives in the hospital.

In the many case histories where lobotomy has had a beneficial effect, particularly for schizophrenic patients, the typical pattern seems to be improvement in personal habits, reduction of hallucinatory or delusional behavior, and improvement in social behavior. But because thought disorders and disorientation persist, the patient cannot really effectively function in the outside world and remains in the hospital environment. For other types of mental illness such as obsessive-compulsive neurosis, lobotomy more often relieved the symptoms to a sufficient degree that the person could be discharged from the hospital and return to productive work.

However, there were occasional disastrous effects of lobotomy (or of other forms of psychosurgery) on personality or intellectual function, and these cases were the source of much of the strong criticism leveled at lobotomy.

But it was not the evaluations for psychosurgery or the ethical issues that led to its decreased use. The event that had the greatest impact on reducing the number of psychosurgical procedures was the introduction of chemical therapy for mental illness. With the advent of the tranquilizers in the mid-1950's, psychosurgery lost its position as the major somatic treatment for severe mental illness. Psychotic behavior that had previously been controllable only by psychosurgical treatment could now be controlled by less drastic, and usually more effective, chemical therapy.

Current Psychosurgery

It is difficult to estimate the current extent of psychosurgery. Much of the psychosurgery today is performed by private practitioners and there is no way to obtain any reasonably accurate figures. There does seem to have been some increase in the frequency of psychosurgical operations over the past 15 years, probably due to the failure of pharmacotherapy to fulfill the earlier expectations for it. Currently, psychosurgeons appear to be concentrating on destruction of portions of the limbic system of the brain, which animal research has shown to be involved in "emotional" behavior. Interruption of the cingulum bundle or removal of the cingulate gyrus—parts of the cortex which early workers thought to be a brain locus responsible for the experiencing of emotions—seems to be a particularly popular procedure. Destruction of portions of the thalamus, or hypothalamus, other structures implicated in emotional behavior, has been used.

Over the past two decades scientists have made considerable progress in defining and understanding the functional role of the frontal lobes and of various other parts of the brain. Almost all of the basic research in this area has been conducted with animal subjects. Extensive studies on stimulation and lesions of various areas of the brain of monkeys, cats, and rats have revealed a complex picture of several specific brain structures that are involved in the control of a variety of emotional and aggressive behaviors.

Taking their cue from these animal studies, psychosurgeons have attempted to eliminate violently aggressive behavior in human patients by small and localized destruction of specific brain areas, or by electrical stimulation of brain areas with surgically implanted electrodes. These psychosurgical procedures are, for the most part, quite different from the "lobotomy" in that they are more firmly based on scientific data about the role of the brain structures, and the destruction of brain tissue is much more limited and localized. In a few instances, the psychosurgeons have, prior to destruction, tried to confirm the role of the specific brain structure they intend to lesion by first electrically stimulating the area to see if whatever behavior they are trying to eliminate can be elicited by the stimulation. In other cases, stimulation of only those brain areas thought to inhibit aggression is performed; any procedure based on stimulation is preferable, because electrical stimulation generally produces less brain damage than lesions. In any case, whether lesion or stimulation techniques are used, the "modern" psychosurgeon attempts to minimize the adverse "side-effects" of the procedures by lesioning or stimulating only a small area of brain tissue, with the hope of eliminating the specific behavior problems but not producing any undesirable changes in personality, intelligence, creativity, or motivation.

Most of the above discussion has focused on aggressive behavior, rather than on the many other forms of mental illness such as schizophrenia or depression. Although psychosurgery is sometimes used in cases of severe depression or other serious mental problems, currently it is principally the uncontrollably aggressive patient who becomes the prime candidate for psychosurgery. The aggressive patient is the one most disruptive and threatening to family, friends, and hospital staff. The serious disturbance of the patient's own life and the lives of the people around him, and the potential for bodily harm that he may inflict on himself or others, often leads to treatment of a drastic nature, especially when other treatments, particularly drugs, seem to fail.

Programs of the National Institute of Mental Health

Since 1947, the National Institute of Mental Health has been strongly committed to a broadly based research program on brain function and behavior. All of the mental states of man are related to physical events occurring within the brain. Emotions such as love, fear, and hate are generally believed to be reflections of chemical and electrical activity in the billions of nerve cells that comprise the central nervous system.

If normal behaviors are produced and controlled by physical events in the central nervous system, then pathological behaviors must be the result of these physical processes operating in pathological ways. In order to understand the root causes of mental disease, it is essential to understand the physiological events that shape and control normal behaviors. Consequently, support of basic brain-behavior research is an integral part of the activities of the National Institute of Mental Health.

One of the first grants awarded by the extramural research grant program of the NIMH was to study the basic neurological aspects involved in the learning process. Since that time the extramural support programs of the Institute have provided a continued and increasing program of support for neuropsychology (brain-behavior) research. In addition, the intramural research program of the NIMH has been in the forefront of research on the physiology of brain function, and especially in the biochemical systems of the brain.

Many pressing and important problems regarding brain-behavior relations are currently being investigated in research laboratories around the country. For example: What chemicals are responsible for transmission of nerve impulses within the brain and how do these chemicals control different forms of behavior? What chemical or physical changes occur when learning takes place or when a memory is recovered from the brain? What anatomical structures and what chemicals are responsible for aggressive behavior, sexual behavior, eating behavior, drinking behavior, and for sleep and dreaming? How are the brain and central nervous system related to the autonomic nervous system which controls many life processes such as heart rate, blood pressure, and a wide variety of visceral functions. What happens to the behavior and cognitive processes of man when portions of the brain are damaged through accident, birth injury, malnutrition or disease? Can functions that have been lost through such disruption of the brain be recovered or taken over by other portions of the brain?

As more and more is learned about control of behavior by the brain, questions asked by brain scientists become more specific and more amenable to experimental tests. We are thus well on the way to building a solid framework for understanding mental processes.

Although most of the brain-behavior research supported by the Institute involves experiments with animal subjects, some studies involve human subjects. These are aimed at understanding the behavioral consequences of altered brain function as a result of war injury, accident, disease or surgery performed because of *clinical* necessity (e.g., removal of brain tumors). Thus, neurological patients are studied with behavioral tests in order to define and understand the sometimes subtle effects of insult to the brain. In these cases there is no experimental manipulation of the brain itself; the subjects are selected on the basis of pre-existing brain dysfunction, damage, or clinical surgery.

The NIMH Study on Epilepsy and Violence

The single project supported by the NIMH which came closest to psychosurgery was a contract, in the amount of $500,000 to the Neuro-Research Foundation in Boston, Massachusetts, which began on June 25, 1971, and terminated on March 31, 1973. The contract involved an attempt to understand and control violent and destructive behavior that is presumed to be a direct result of brain dysfunction.

The research conducted under this contract was based on an hypothesis that some forms of mental illness, especially those characterized by violence or hyperactivity, are the direct result of organic brain disease. Based on evidence from animal studies showing relationships between the limbic system and emotional behavior, the limbic system of the brain is usually singled out as the area most likely to be involved. There are also some scattered and anecdotal reports in the clinical literature on the effects of damage to the limbic system by tumors or by war injury or accident in which a predominant symptom is violent behavior. A few studies have purported to show that there is a high incidence of abnormalities in the electrical brain activity (EEG) of criminal populations, particularly in those subjects who have repeatedly committed senselessly violent acts. Unfortunately, interpretation of the EEG is a difficult task, and the meaning of any given type of "abnormality" is an open question in view of the present inadequate understanding of the electrical processes of the brain. In any case, the main point is that the psychosurgeon believes that there is an organic basis for disordered behavior.

Certain forms of epilepsy have been used by some psychosurgeons as a model for explaining what happens in the brain during some violent behavior. In fact, there have been unconfirmed reports that the emotional and behavioral states preceding some types of epileptic seizures correspond to the behaviors exhibited by persons just prior to the commission of a violent or aggressive act. In a few cases there does appear to be a clear relation between epilepsy and violence, with patients displaying both conditions. However, even in a case where a patient clearly has epilepsy and is also subject to rage attacks, the nature of the relation between the two conditions is unclear. Frequent and violent seizures and the accompanying psychological phenomena are devastating experiences; it seems likely that at least some of the violent behavior exhibited by epileptics is triggered by frustration and fear and not directly by any electrical seizure activity in the brain.

The group at the Neuro-Research Foundation hypothesized that for some of those persons who exhibit periodic uncontrollable violent behavior, a process akin to psychomotor epilepsy is responsible, but the source of such brain dysfunction lies deeper in the brain in the limbic system, and thus the primary symptoms are emotional rather than the automatic and more subtly-disturbed behaviors seen in psychomotor epilepsy. The intent of this group was to try to identify the organic dysfunction which they presumed responsible for violent behavior. The main technique is used to implant electrodes in various parts of the brain and to try to identify abnormalities, particularly seizure-like discharges, which will correlate with aggressive behavior. If an apparent focus of seizure activity is found, and if this seizure activity appears to correlate with outbursts of aggressive behavior, then a small lesion may be made to destroy tissue at the seizure focus. Ideally, this restricted lesion will stop the seizure activity at its source. Whether or not this surgical procedure constitutes "psychosurgery" as defined in the beginning of this paper is debatable. Although the surgery is done to treat aggressive behavior, it is primarily intended to stop the seizure activity of the brain.

One factor that makes this kind of research especially difficult is that simply admitting an epileptic patient or a person exhibiting violent behavior to a hospital and placing him in a treatment environment may greatly reduce the frequency and/or severity of the symptoms, in the absence of any medical treatment or drug regimen. Thus, it is difficult to study a phenomenon that often disappears, or appears much less frequently than before, as soon as the patient is put in a treatment environment.

Factors such as this led the research team of the Neuro-Research Foundation to focus more on defining the environmental situations that trigger seizure activity or aggression and to test the value of psychiatric treatment, such as group therapy, in helping patients to deal with and control their periodic outbursts of violent behavior. In fact, during the course of this contract, no psychosurgery was carried out (although one chronically epileptic patient did receive a brain lesion). The research emphasis was on electrical recording studies, correlation of electric brain activity with various behaviors, and psychiatric treatment.

One of the primary issues in this area, as in all research projects dealing with human subjects, is the protection of the rights of the individual. A project which involves medical or surgical treatment in combination with psychiatric treatment, and deals with patients who are severely debilitated in terms of their capacity to function in society, presents especially thorny issues of protecting the physical and psychological well-being of the patient. An equally important ethical issue is the scientific merit of the proposed research, since if the studies are not scientifically sound and are not likely to yield important and useful data, then the human subjects have been exposed to medical or psychological risks that are not outweighed by the potential benefits.

In all candor, it must be admitted that there was considerable controversy during the review of this project; indeed one would be concerned if there were *not* controversy in the review of a project so fraught with ethical complexities. Ultimately, however, the project was approved by a committee of five senior scientists and clinicians from the Harvard Medical School, Massachusetts General Hospital, and other hospitals in the Boston area, and some of the controversial issues that arose during the NIMH review of the project were resolved by extensive further documentation and correspondence provided by the Neuro-Research Foundation. The award was made with the proviso that there be a thorough and continuing examination of the procedures and results of the project. It also is of interest that reviewers of the proposal felt that an important byproduct of the project was an opportunity to develop procedures to provide the necessary broadening of the processes of review increasingly demanded by research and development in the behavioral and biological sciences.

The procedures established for the protection of the human subjects in this project were designed to assure that the patients had problems severe enough to consider them as candidates for drastic treatment measures, that the patients were fully informed (insofar as possible) as to the potential risks involved, and that every conceivable measure of protection of the patients' rights and well-being was exerted. For each and every patient admitted to the program, a review committee composed of scientists and physicians not associated with the Neuro-Research Foundation would review the individual case and approve or disapprove his admission to the program. If a patient were admitted to the program, it would be only for psychiatric and medical evaluation studies, possibly including depth electrode studies of brain seizure activity. If, on the basis of these studies, the investigators felt that any brain lesioning procedures were warranted, additional review by another outside committee would be required.

During the tenure of this contract, continuous monitoring of the project was conducted by NIMH staff and outside experts, including regular quarterly reports, continued contact by phone and mail, and periodic site visits. The emphasis on nonsurgical and psychiatric treatment provided encouraging indications that at least some patients exhibiting uncontrollable violent behavior can be helped without resorting to irreversible surgical treatment.

Psychosurgery, Behavior Control, and Ethics

With very few exceptions, medical scientists and clinicians oppose the "classical" lobotomy. As previously discussed, there is no sound evidence that it is a worthwhile procedure, and it too often has deleterious effects on personality. Actually, lobotomy is not the issue; as techniques for more refined brain recording, stimulation, and lesioning have become available, and as the literature on animal brain research has begun to define, however vaguely, functions of specific brain areas, practitioners are more frequently considering surgical treatment for behavioral problems.

As with any controversial issue, there are extreme opinions pro and con psychosurgery. Some opponents argue that psychosurgery in any form and for any behavioral or mental disturbance—regardless of its severity—should be outlawed. At the other extreme, some proponents argue that psychosurgical procedures should no longer be considered research but constitute routine and accepted treatment for a diversity of behavioral disorders ranging from childhood hyperkinesis to homosexuality. A middle stance would hold that psychosurgery might be of potential benefit and should be studied only for its use in cases of extreme mental illness, especially those that are life-threatening to the patient or those around him and that psychosurgery should be performed only after extensive attempts at alternate modes of therapy had failed.

Critics of psychosurgery cite the ethical and moral issues involved in changing or controlling the behavior of individuals. Psychosurgery, because of its dramatic nature, has become a "lightning rod" for concern and criticism about behavioral control. Although psychosurgery is a powerful means of changing behavior, the ethical problems posed by the modification of behavior with drugs or psychotherapy are probably of greater import because these means of control are available to a much wider range of potential "abusers" than are the techniques of psychosurgery.

These developments, and other advances such as techniques for the prolongation of life, bring with them ethical complexities heretofore unheard of. Medical ethics has never been, as some mistakenly believe, a matter of good versus evil or right versus wrong. It has always been a matter of when, where, and who draws the line as to whether a given medical procedure is helpful, harmful, or warranted, and whether the potential benefits of any course of treatment outweigh the risks.

While, on the one hand, society is clamoring in certain fields for the right of every individual to treatment, an almost equally loud cry is beginning to be heard about the individual's right to death. Even more complicated ethical issues arise when the patient is part of a scientific study. While good clinical practice demands that the individual always be a patient first, scientific studies often demand the withholding of an experimental treatment from some patients while providing it to others in order to compare the effectiveness of the new treatment with older treatments or with no treatment. However, there are those who dispute the right to withhold treatment of potential value from anyone under any conditions.

Department of Health, Education, and Welfare Policy

There are no simple answers to these problems. There is an increased public awareness of the extent and nature of these difficulties and some enthusiasm for the establishment of bioethics commissions which would serve as watchdogs and would devise suitable guidelines. Still others believe that it is best if the professions involved establish their own ethical criteria and monitor their own activities. A middle stance would hold that while it is most appropriate for the various professions to establish their own ethical principles, in all instances this should be done with the involvement of other professions, and with appropriate representation of laymen and consumers.

In addition to these ethical concerns, the securing of informed consent poses a difficult problem.

DHEW guidelines describe the basic elements of an informed consent as follows:

1. A fair explanation of the procedures to be followed, including an identification of those which are experimental;
2. A description of the attendant discomforts and risks;
3. A description of the benefits to be expected;
4. A disclosure of appropriate alternative procedures that would be advantageous for the subject;
5. An offer to answer any inquiries concerning the procedures; and
6. An instruction that the subject is free to withdraw his consent and to discontinue participation in the project or activity at any time.

Because these guidelines require that any institution conducting contract or grant-supported research involving human subjects must establish a professional review committee, to assure that the research protocol adequately fulfills the policy for protection of the subjects. Their existence has produced a beneficial "spill-over" of ethical policy to research and treatment activities not supported by DHEW.

Safeguards for the Future

The ethical and moral problems posed by current medical, biological, and behavioral techniques are of considerable concern to Government agencies as well as the health professions, the scientific communities, religious groups, the Congress, and the lay public. Knowledge, or at least the application of knowledge to wield political or social power, has always been a potentially dangerous concomitant of scientific inquiry. We must somehow evolve a system of technology assessment whereby the state of knowledge can be assessed and its readiness for application can be addressed within the context of relevant social, human, and ethical issues. Such a system would assure the timely application of relevant technology and help prevent the premature use of those techniques not thoroughly explored for their human and social implications.

We believe that the answer to the dangerous use of knowledge is the creation of new knowledge, combined with a sensitive, rational, and humanitarian perspective on the applications of that knowledge. It is also important to broaden the training of scientists and practitioners to include such ethical issues and humanities.

In recent years professional societies and private foundations have developed a variety of programs to deal with medical and behavioral ethics. One of the most active private groups is the Hastings Center Institute of Society, Ethics, and the Life Sciences. Founded in 1969 with support from several philanthropic organizations and individuals, the Institute has organized a variety of seminars on ethical issues, has established an experimental teaching program on medical ethics at Columbia University, and has a dedicated and professional staff conducting research programs on ethical issues in the areas of behavior control, population control, death and dying, and genetic engineering. The National Science Foundation has provided support for the Institute's program of behavior control research. Organizations such as the Hastings Center Institute merit continued support, both from private and governmental sources.

The National Academy of Sciences-National Research Council has established a Committee on the Life Sciences and Social Policy. This committee, composed of a prestigious group of lawyers, scientists and historians, is concerned with identifying the issues and problems emerging from advances in the biological and medical sciences. The Committee has considered such issues as organ transplantation, behavior modification by drug administration to children, and fetal diagnosis and will issue a report of its deliberations in the near future. The prestige of the National Academy of Sciences and the eminence of the Committee members assures that this group's activities will be of considerable influence in the field of bioethics.

The American Psychological Association has just completed an extensive project to develop a report on ethical principles for the conduct of research with human participants which goes into unprecedented detail on potential risks and recommendations for protection of human subjects. This ethical code promises to be very influential as a model for other behavioral sciences.

Conclusion

Continued research in medical science and the development of new medical technologies promise to present us with unprecedented ethical dilemmas that must be faced by the Government, scientists, medical practitioners and the public. The issues are, and will be, complex ones for which there are no easy answers, and deal with matters of law, philosophy, religion, science, consumerism, and public policy. The answers, when they do come, will not derive from either emotional attacks or a blind faith in the sanctity of science and medical practice but from a reasoned analysis of all facets of the issues by concerned, sensitive, and rational representatives of the diverse groups involved. The answers to the issues of psychosurgery will depend heavily upon scientific advances in our studies of the brain and behavior. Some day it may be possible to say that in the light of our expanded knowledge, the potential benefits of psychosurgery far outweigh any possible risk to the human subjects—but that day is not yet. We are sobered by the thought of how very much more there is to know about that marvelous structure, the human brain.

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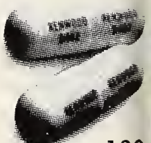

Opens new possibilities for the patient with cerebral ischemia due to vasospasm

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Neurosurgeon's Response to the U.S. Mental Health Review of Psychosurgery

William Beecher Scoville, M.D.

I have reviewed with great interest the article from Washington's Institute of Mental Health on "Psychosurgery: Perspective on a Current Issue."[1] This article attempts an objective definition and evaluation of past and present psychosurgery, now named "psychiatric surgery," describing the first rather crude interruption of all connections from the prefrontal brain to the thalamus. From the beginning all surgeons attempted ever more selective sections with lesions limited to the medial portions of the frontal lobe (cingulate gyrus); to the posterior-inferior surfaces of the frontal lobe (orbital cortex); and to the more recent removal of medial portions of the temporal lobes (amygdala); and the concentrated sensory nuclei of the upper brain stem, hypothalamus and thalamus and their connections to the fornix and internal capsule. As the authors quite rightly pointed out, even the crude early operations made the patient a happier and more equilibrated social being than existed when he was hallucinating, defecating and assaulting in back wards of State Hospitals. And now, actual psychiatric surgery has progressed so far and so selectively that it can be used in people no longer termed psychotic but who are deeply suffering from suicidal depression, from agonizing anxiety, or from unbearable compulsive and repetitive thoughts. Such symptoms will have rendered them unable to perform any work or to live with their fellow beings and their suffering will have been very intense indeed.

As the authors have also pointed out, the reason for the decline of lobotomies in the fifties was not its abuse but rather the discovery of electro-shock therapy and the newer sophisticated medical therapies, especially the anti-depressive and anti-schizophrenic drugs permitting sufficient remissions to bring the patients out from those hospital back wards. No legislative nor ethical actions were required to reduce the use of psychiatric surgery to a miniscule number—a drop from many thousands of operations to less than fifty per year throughout the whole of the United States. There was no problem of surgical disasters for some 25 years, nearly a generation gap. In fact shock therapy and some of the extreme drug induced comas resulted in more temporary personality changes than had selective surgical lesions.

It was not until a new generation of psychiatrists discovered even the newest drugs and refined shock therapies still failed to sufficiently benefit some cases of intractable and recurrent depressions and of perpetual anxiety and obsessions. Most suicides are from depressions and the worst obsessive-compulsive patients may lock their children in their bedrooms for days on end for fear of infection, and others have made continous round trip circuits from their home to their place of work again and again all day long for fear they might have run over a child without knowing it. These devastating illnesses are those which are benefitted by selective surgical operations in specific areas of the brain. So also are agitated states of old age, thought to be senile dementia, but rather surprisingly correctable by making additional destructive lesions in those brains already impaired by arteriosclerosis. These patients become calm and happy and without intellectual loss. Schizophrenic patients are probably more benefitted by drugs than by surgical lesions, but there are still some forms having a strong element of intense suffering and mental anguish with depression which deserve surgery as both a lifesaving measure and restoration to happiness and escape from permanent commitment.

These statements are true only if both physicians and the public realize that psychiatric surgery, because the operations are irreversible, must always be preceded by prolonged psychotherapy in the hands of experienced psychiatrists; by a full trial of the most recent drugs; and possible trial of a limited number of shock treatments. Warning is given that too much shock treatment may cause the same type of blunting of higher mental sensitivities that head injuries or the old-fashioned complete lobotomy caused, hence should be used only by psychiatrists well versed in its dangers. E.S.T.'s chief value is of course in acute depressions whether manic-depressive, reactive, or schizo-affective.

What cases do not warrant psychiatric surgery even after trial of everything else? They are: 1) constitutional psychopaths, and let us remember that most lifelong criminals are psychopaths genetically or constitutionally born without a sense of moral obligation to society, and totally lacking in feelings of guilt or sympathy toward their fellow creatures; 2) social rebels who are either spoilt children or the product of environmental poverty and misfortune. They never warrant psychosurgery because they are not mentally ill but rather are reacting against an

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unfortunate environment or the hard knocks of life. They may rebel improperly but not psychotically and treatment should of course attempt to improve the environment rather than change the brain; 3) children with behavior problems and even violent temper outbursts almost never warrant surgery because it is irreversible and there is always the chance that children will outgrow their troubles aided by drugs, hormones or loving discipline. Anorexia nervosa is an exception.

There are other exceptions: those very rare cases of organic temporal lobe epilepsy exhibiting symptoms of wild rage and assaultiveness occasionally warrant removal of a portion of the temporal lobe. Such a disease almost never causes sexual and assaultive crimes as sentimentalists like to think. Social alcoholics are not benefitted by psychosurgery, but those who take drugs or liquor to escape from unbearable anxiety or somatic hysterical compulsions are benefitted.

Physiology of Surgical Benefits

Psychiatric surgery should be limited only to those cases exhibiting an *overactivity* of emotions as manifested by depression, anxiety or guilt feelings; or by an organic derangement of sensory input manifested by delusions, hallucinations and thought disorders. Surgical lesions may diminish these exaggerated feelings and sensory input, resulting in a more normal social being. The reason surgery should be done on people only with such overactivity is that every psychosurgical lesion, no matter how selective, is destructive of some function. If such surgery is done on normal people it would blunt them to a measurable extent and if done on those with a constitutional absence of feeling tone and social obligations as in psychopaths it would obviously render them so much the worse. As Walter Freeman once remarked, he could find no benefit from psychosurgery on sexual deviates and when he carried out his early lobotomy operation on a "Peeping Tom" the only result was to change his peeking from secret back alleys to open front verandas.

In conclusion, we should define the ethics for psychiatric surgery as constituting the same ethics that we carry out in all surgical operations and in fact all methods of caring for the sick. If psychosurgery, even by selective "blunting," lessens the intolerable symptoms causing a person to be antisocial or to commit suicide then it is ethically proper, while if the operation makes this person less happy and less adjusted to social living then it is unethical. The decision as to whether psychosurgery is desirable can only be decided by the psychiatrist, the surgeon and the patient or his family—not by legislators, politicians or psychologists. They can determine only the legal penalties and the psychic loss (their province) in all forms of surgical and medical care of the sick—be it for cancer, for trauma or for mental illness.

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Record 14,436 Students Begin Medical School

A record total of 14,436 first-year medical students was expected in the fall of 1974 in the 114 medical schools across the country.

Total enrollment is estimated at 53,735 by the American Medical Association's Department of Undergraduate Medical Education. Both totals represent a slight increase over 1973 when 14,182 first-year students, out of a total of 50,912, were enrolled in the same 114 schools.

The new enrollment figures were reported in a September issue of *American Medical News,* the AMA's weekly newspaper.

This is the first year in recent memory in which no new medical schools are admitting students for the first time, say AMA staff members. Some schools are scheduled to open their doors next fall or in 1976, however.

Expansion of several schools, plus admission of new classes by fledgling schools less than four years old, accounts for the increase in enrollment.

A total of 107 of the nation's medical schools will be graduating about 12,857 new M.D.s in the spring of 1975—compared to last spring's total of 11,613 M.D. graduates from 103 medical schools.

The four new medical schools which will be granting degrees for the first time this academic year are the University of Hawaii in Honolulu; Brown University in Providence, R.I.; the University of South Florida in Tampa; and Southern Illinois University in Springfield. The former two were two-year schools which have expanded to degree-granting status; the latter two are new institutions which admitted their first students in 1971.

The total of degree-granting institutions is expected to increase by 110 by the 1975-76 academic year, AMA staff members reported, when three more schools in development reach the graduation stage.

The AMA annual fall survey of medical schools no longer breaks enrollment down into four classes, since a large proportion of the schools now offer a more flexible curriculum. Some 42 medical schools now permit students to complete work in less than four years, and of these, seven require MD completion in three years.

The Drug Approval Process and the FDA

Alexander M. Schmidt, M.D.

A. OVERVIEW

The Federal Food, Drug, and Cosmetic Act states that no new drug may be marketed in the United States unless a new drug application (NDA) has been approved for that drug by the Food and Drug Administration. In order to have an NDA approved, a manufacturer must submit substantial evidence showing the safety and effectiveness of the drug under the use proposed. The law permits FDA only 180 days to render a decision on an application. Frequently, however, if deficiencies are found, the company and FDA agree to an extension of time to permit additional documentation to be submitted before a final decision is made. Otherwise, FDA must either approve the NDA or disapprove it. The grounds for denying or disapproving an application are specified in the law and in detailed regulations.

The process by which a decision is made regarding an NDA actually commences much earlier than submission of the NDA itself. The law requires that any research on a new drug in human beings can be done only after a notice of claimed exemption for investigational new drug (IND) has been submitted to the FDA and at least 30 days have expired without notification from the FDA that use may not commence. Thus companies contemplating marketing of a new drug will generally have already done clinical trials to establish safety and effectiveness under one or more IND's. Although the function of the IND is primarily to prevent exposure of the human subjects engaged in the research to unjustified and unnecessary safety risks, a secondary purpose is to allow FDA to evaluate continuously the process by which a firm gathers data about a new drug prior to submission of an NDA.

The decisions to permit research under an IND and to approve or to disapprove an NDA originate within an FDA drug review team. This team is comprised of a medical officer (generally a physician with some speciality), a chemist, and a pharmacologist. It may include other persons with expertise in biostatistics or specialities of medical practice related to the patients in whom the drug is intended to be used. These individuals perform the ongoing FDA review of all documents relating to a specific drug, conduct the various reviews necessary to make an institutional decision, and make the scientific recommendations to the management of the Agency.

In recent years, to expand the competence of the Agency and develop closer contact with the medical and scientific community, the FDA has developed a series of advisory committees made up of experts in particular fields. These committees review important scientific decisions and advise the Agency on critical questions. Often matters of difficulty are referred to them by the FDA drug review team, or by others in the drug review process, for guidance.

All matters involving IND's and NDA's are subject to supervisory review. Within the Bureau of Drugs there is an Office of Scientific Evaluation. This office includes six divisions into which all of the major drug categories are assigned. Drug review teams are organized within these divisions. Thus, the recommendations of any drug review team are first reviewed at the division level and must be subject to the approval of the division director. Thereafter, all approvals and disapprovals of new drug applications and all orders to terminate IND's are reviewed by the Director of the Office of Scientific Evaluation of the Bureau of Drugs. Finally all decisions to approve or disapprove significant NDA's and to terminate IND's are ultimately made by the Director of the Bureau of Drugs.

B. FDA DRUG REVIEW TEAM

(1) Composition and Activities

To arrive at sound decisions in evaluating IND's and NDA's, the Agency has developed a team review process that involves medical officers, pharmacologists, chemists and, whenever necessary, biostatisticians and members of other disciplines. Where possible, the same reviewing team follows a drug from the IND phase, through the NDA, and into the post-marketing period. The functions of each member of the team are related to their expertise.

The reviewing chemist evaluates those sections of IND's and NDA's dealing with chemical components, manufacturing, processing, package and control operations, and the technical aspects of labeling.

The reviewing pharmacologist evaluates the adequacy of animal pharmacological and toxicological studies and, based on these studies, assesses the relative risk involved in administering the drug to humans.

ALEXANDER M. SCHMIDT, M.D., is Commissioner of the Food and Drug Administration in the Public Health Service, HEW. This article is the Editor's abstract of Dr. Schmidt's statement before the Senate Subcommittee on Health, September 25, 1974.

The medical officer reviews proposed clinical trials of new drugs not only from the standpoint of safety, but also to determine if a pharmacologic rationale has been adequately demonstrated for the drug, and if the protocol is properly designed so that the study could be expected to achieve the proposed objectives. Medical review of an NDA must evaluate the clinical studies submitted and recommend whether they are adequate and well controlled and whether they suggest safety and effectiveness. The medical officer reviews the findings of the chemist and pharmacologist and makes recommendations regarding the benefit expected from the drug and the risks involved.

The members of the FDA drug review team act independently within their respective disciplines, as well as collectively as a team. Initially they report, respectively, to the Supervisory Chemist, Supervisory Pharmacologist, or Medical Officer Group Leader within their Division. After each discipline has prepared its review, the team meets with the Medical Officer Group Leader to prepare joint recommendations to the Division Director. Throughout the review, members of the team consult with each other, sharing insights and information.

(2) Assignment of Individuals to Teams

The selection of individuals for the team is made independently by the Supervisory Chemist, Supervisory Pharmacologist, and Medical Officer Group Leader within that Division for assignment to a reviewer in each of those disciplines. Assignments to reviewers are generally based on (1) the area of expertise of the reviewer; (2) his experience with certain categories of drugs; (3) his experience in reviewing drugs; and (4) an acceptable distribution of the workload.

(3) Recruitment of Professionals

The quality of the drug review process depends on the skills of our staff, our advisers and our executive leadership—and their level of expertise and the quality of their judgments. The Agency has devoted considerable effort to attract the kinds of talented professionals to FDA's vital programs.

C. USE OF ADVISORY COMMITTEES BY FDA

(1) General Background

There are a number of advantages to the use of advisory committees, both to FDA and to the public:

1. FDA gains access to highest levels of scholarship in the scientific community and in other Federal agencies. State-of-the-art knowledge is contributed by individuals engaged in research or clinical practice.

2. Regulatory decisions are recognized by affected parties as having included advice from leaders in the medical, academic, and scientific communities, all of whom are visible and accountable.

3. Participation by the scientific community and the public in meetings improves the credibility, acceptability, and influence of Agency decisions because the public recognizes the integrity of an open decision-making process by competent individuals.

4. In selected areas where the Agency lacks intramural expertise, consultation with technical committees or panels permits prompt access to the expertise required for a responsive solution to the regulatory problem.

5. The rotational nature of committee memberships insures the availability of individuals who are outstanding in their fields.

6. Exposure of consultants, committee members, and the public to the Agency's deliberation and problems promotes dissemination of information which might otherwise be confined to official circles.

7. The advisory committee meeting itself aids decision-making by providing a formal setting for comprehensive review of data, scientific discussion, and resolution of problems.

(2) Activities of Advisory Committees

Data for review are supplied to the committee members in advance of the meeting together with the questions to which we wish the committee to respond. In some cases, a subcommittee, and, frequently, an individual committee member are appointed by the committee chairman to review the data in depth and report to the entire committee. In certain cases involving IND's and NDA's, and always if requested, we furnish the available raw data to advisory committee members for their review. It is particularly important that those members requested to do an in-depth review acquaint themselves with the raw data on the important clinical trials. Before each meeting interested members of the public and of the regulated industry are invited to make a presentation at the scheduled meeting. When specific firms are involved, they are asked to submit backup data in advance for review by the committee. Oral presentations are made not only by the public and the industry but also by FDA staff. The recommendations made by the advisory committees are based upon cited evidence supporting their conclusions.

In order to protect trade secrets and other privileged information, members are carefully briefed as to the steps which should be taken to accomplish this. Explanations are provided as to what is protected under Federal laws.

D. DEALING WITH INDUSTRY AND PUBLIC

(1) Contacts with Sponsor

The Food and Drug Administration believes that any citizen has a right to talk to or meet with the employees of the Agency concerning a matter of interest to that citizen and which is within FDA's jurisdiction. This applies to industry, consumers, and physicians.

Certainly, drug companies which have submitted IND's or NDA's to the Agency are entitled to meet with the Bureau of Drugs. During the course of the drug review process, there are usually frequent contacts with the sponsor. These meetings should not be viewed as a subversion of the Agency's objectivity, but rather as an opportunity for exchange of information which often helps improve the quality of submissions, facilitate correction of deficiencies, anticipate and resolve differences and thereby reduce subsequent litigation.

(2) Public Access to Information

It is important for the FDA to have a public information policy which is understood by our own employees, as well as by the public. FDA's policy is to be as open as possible on the information in our files, in accordance with the policy behind the Freedom of Information Act. We do not invoke the exemptions to the Act except where there is sound reason to do so. Certain criminal statutes flatly prohibit us from releasing certain information including trade secrets.

(3) "Pressures" on FDA by Industry and Other Outsiders

By far the greatest pressure that the Bureau of Drugs or the Food and Drug Administration receives with respect to the new drug approval process is brought to bear through Congressional hearings. In all of our history, we are unable to find one instance where a Congressional hearing investigated the failure of FDA to approve a new drug. The occasions on which hearings have been held to criticize approval of a new drug have been so frequent in the past ten years that we have not even attempted to count them.

At both the staff level and managerial level, the message conveyed by this situation could not be clearer. Whenever a difficult or controversial issue is resolved by approval, the Agency and the individuals involved will be publicly investigated. Whenever it is resolved by disapproval, no inquiry will be made. The Congressional pressure for negative action is therefore intense, and ever increasing.

This can be remedied only by Congressional recognition that the failure to approve an important new drug may well be extremely detrimental to the public health. Congress should be as willing to investigate charges that FDA is not approving important new therapeutic advances as it is to hear charges that we resolve close issues in favor of approval. Until perspective is brought to the legislative oversight function, the pressure from Congress for FDA to disapprove new drugs will continue to be felt, and could be a major factor in health care in this country.

E. THE FINAL DECISIONS

(1) The Risk-Benefit Judgment

The judgment that must be made by FDA in reviewing an IND in order to justify the proposed testing is whether there is sufficient evidence of safety derived from preclinical (animal) studies *and* sufficient promise or prospect of achieving medically significant effects to warrant introduction to human trial. Similarly, at critical phases in the investigational process. the same kind of judgment is made about continuing such trials. NDA review necessitates an evaluation of all available data to permit a conclusion as to whether the safety and effectiveness of the new drug has been demonstrated to the satisfaction of responsible Agency officials. Continuing post-NDA review of marketed drugs permits reconsideration of the NDA approval decision with a view to revising the labeling or withdrawing the drug from marketing.

(2) The IND

The prime purpose of the IND is to protect the safety of investigational subjects while developing the data on safety and effectiveness necessary to permit the marketing of the drug. A corollary responsibility of IND is to ensure the appropriateness and scientific design of studies under the IND so that the IND review process may efficiently anticipate and prevent problems which might arise in NDA review.

The considerations on which the FDA makes its decision to permit or restrict initial research include:

The protection of the human research subject.

The adequacy of animal studies already completed and analyzed.

The scientific merits of the research plan.

The qualifications of the investigator.

(3) The NDA

The "critical phase" conferences held during the IND process just described are a recent development. It is hoped that, by the last conference, the FDA and the sponsor of the IND will be in basic agreement about the kinds and adequacy of data on which the NDA will be based, so that the NDA will be simply a formal pulling together and organization of data acquired through many kinds of trials conducted over several years of drug development.

The NDA must contain all information, both favorable and unfavorable, which the sponsor has obtained through investigations relating to both the safety and the effectiveness of the new drug. Each NDA consists of about 2 to 15 volumes of summary material accompanied by about 10 to 100 volumes (occasionally up to 400 volumes) of raw data.

By law, the FDA has 180 days in which to review the NDA and either approve or disapprove the application. The FDA may withhold final action on the NDA pending the compilation and submission of additional data, however, if the applicant agrees to the extension. The grounds for refusing to approve an application are specified in the Act and regulations. Where the FDA proposes to refuse to approve the NDA, the applicant is notified of an opportunity for a hearing on the question of whether the NDA is approvable.

(4) Subsequent Review

Responsibility of the Food and Drug Administration for the safety and efficacy of drugs continues after marketing approval is given. If at any time clinical or other scientific data lead reviewers to conclude that the safety or efficacy of a marketed drug is different than when approved, labeling changes may be effected and, in some instances, actions may be taken to withdraw the drug from the market. Information which may result in these actions may come to FDA from its own records and reports (including adverse reaction) which are required by regulation, spontaneously received information, post-marketing studies (required for some drugs), FDA laboratory testing facilities or new chemical and pharmacological data.

We do consider the present review system to be far superior to systems used in the past, although we still wish to improve it. In the 1950's, pharmacology, chemistry, and medical reviews were carried out in different divisions. The medical officer received the recommendations of the chemist and pharmacologists, and issued a disapproval letter without additional review. This produced a real double standard for review, for only letters of approval were sent through channels to the Commissioner for signature. Disapprovals could be issued by the reviewing medical officer with no supervisory review. In the early 1960's, supervisory approval of the medical officer's recommendations for disapprovals was developed. In 1966, chemistry, pharmacology, and medical reviewers were brought together although IND's and NDA's were still handled by separate divisions. Since 1970, IND's and NDS's have been evaluated in the same divisions so that a reviewing team could follow a drug through the IND and NDA stages into the post-marketing period, and all letters of approval and disapproval must be reviewed through the same channels to the same supervisory levels.

Where FDA turns down a drug, the Agency must have adequate legal, as well as scientific, documentation of its reasons, sufficient to sustain the Agency's judgment in an administrative proceeding or a court action. The need to have such a record before final disapproval of an NDA may result in requests by supervisory officials for justification of non-approval recommendations. In this regard, some reviewers may perceive a more intensive scrutiny of disapproval recommendation than for approval recommendations. This perception is not evidence of a double standard, but proof that FDA complies with legal mandates instead of acting capriciously in making drug review decisions.

Due Process in Hearings on Staff Privileges

Jay H. Hedgepeth

The judicial literature on medical staff privileges continues to grow. The Supreme Court of Hawaii has made an interesting contribution that may merit special attention.[1]

The case involved a neurosurgeon who, previously and after a hearing, had been denied staff privileges at a private, not-for-profit hospital. In 1965 he reapplied for privileges and, in 1966, was granted "temporary surgery privileges for one year under observation by other doctors." At the end of that year an investigation was conducted into his performance and, on recommendation of the investigating committee, the governing board declined to renew his privileges. The surgeon was granted a hearing, and the governing board adhered to its original decision.

The physician then filed suit alleging conspiracy, defamation, and antitrust violations, all of which the appellate court found to be "without merit." Nevertheless the appellate court found that the physician had been denied "procedural due process" and, one must infer, had the right to a rehearing before the governing body and should be given an injunction pending final decision by the governing body. The injunction would reinstate him to his probationary or, as the court termed it, "temporary" privilege status.

Jurisdiction of Courts, Discretion of Boards

At the threshold of its decision, the appellate court determined that it had jurisdiction to undertake judicial review of the medical staff privilege decision of a private hospital board that had received both state and federal construction funding and "had more than nominal governmental involvement in the form of funding." Although it gave rather full discussion of the circumstances that may confer the right of judicial review, the court specifically reserved any decision as to (a) what other types of "governmental-public involvement" might confer jurisdiction for judicial review or (b) whether or not a "truly completely private" hospital board decision would be subject to such review.

In so holding, the court recognized that "broad discretionary power" should be vested in hospital governing boards in granting or denying staff privileges. It specifically denied that the mere fact of medical licensure was prima facie qualification of a physician for medical staff privileges: "Apparently the state licensing procedure does not distinguish between general practitioners and specialists such as neurosurgeons. Nor does the state licensing system provide for adequate periodic review of a doctor's skill and performance, both of which are of primary importance to the beneficiaries of the services of the hospital and doctors involved, the patients themselves."[2]

The court also recognized that mere professional skill alone is not a sufficient qualification for privilege since "[t]he absence of a compatible team working together could impair the doctor's performance and consequently undermine the effectiveness of the treatment given the patient." The court further stated that such methods of screening and reviewing applicants for staff privileges were observed throughout the country "in terms of qualifications, current skills, performance, personality and character."

Despite such broad discretionary power, the court proceeded to find that the physician had not received "procedural due process" at the hands of the hospital governing board. The court did not reach the issue of whether or not the governing board's decision was based on insubstantial evidence or resulted from an abuse of discretion for being arbitrary, capricious, or unreasonable.

'Procedural Due Process'

The court termed as self-defeating any "excessively burdensome procedures" in the screening process, but it held that minimal observance of procedural due process would include the following:

- The applicant should be given notice that a hearing is available to him, and a hearing must be provided before the "deciding board,"[3] although the hearing need not conform to either judicial or quasi-judicial requirements.
- Timely notification of specific charges must be given that will permit an applicant to prepare an adequate defense. (The physician in this case was "merely read an indictment of general allegations at the hearing.")

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- Where there had been sufficient opportunity to observe his professional performance, any failure of performance should be pointed out in the charges.
- The applicant must be permitted to call his own witnesses (and presumably to cross-examine those witnesses produced against him).
- The decision of the governing body must be based on evidence presented at the hearing itself and not on private information of its members; otherwise, the applicant would not know what material he might need to explain, refute, or mitigate.[4]
- The decision and its basis should be written, "thus providing a record for judicial review."

Few courts had specifically ruled as to whether or not a medical staff applicant has an absolute right to be attended by his attorney when the medical staff bylaws do not specifically confer that right. This court held that the right of participation by the applicant's counsel should be discretionary with the hospital governing board, observing that an applicant could consult with an attorney prior to a hearing but adding the qualification that: "Participation of counsel would probably not be necessary unless the hospital's attorney is used in the proceedings or the extreme nature of the charges involved indicated that representation by an attorney would be advantageous."[5 7] Cautious medical staffs and governing boards may wish to avoid this issue by permitting the applicant's attorney to participate; this also may contribute to decorum and to efficient proceedings.

The Issue of Prejudgment

The court found that the governing board had prejudged the application in advance of the hearing. It condemned this action as follows: "It is clear from the record of this case that the hospital board made its decision as to the renewal of appellant's privileges prior to the ineffective hearing granted appellant. Such a procedure cannot be considered satisfactory. A final decision to revoke privileges or not reappoint, made by the ultimate governing body, the hospital board, must come after the requisite hearing is provided. In order for the board to function as an objective decision-making body in its capacity as grantor of staff privileges it must not be tainted by its own premature decisions prior to the hearing."

The appellate court did not disclose, however, how the governing board might have avoided prejudging the case or how it could avoid "prejudice" in reconsidering the application after remand to the lower court. The merits of the application were not explored by the appellate court, and there is no way of knowing whether or not the governing board could have avoided any prejudgment. There are occasions in which an applicant's performance may be calculated to induce a sentiment against his interest before a hearing. If prejudgment or even bias or prejudice were to be grounds for disqualification of the governing board, a shrewd applicant might adopt strategy to provoke disqualification of the governing board on that basis. One also might consider the fact that a governing board frequently has been at least placed on inquiry or moved to a tentative judgment by the applicant's performance or record or, in many cases, a hearing could never have been occasioned.

A medical staff committee or governing board faced with the possibility of a charge of prejudgment, bias, or prejudice may do well to consult the hospital attorney who, in turn, may wish to consult such authorities as 39 A.L.R. 1476 and 97 A.L.R. 2d 1210, 1222.

REFERENCES

1. *Silver v. Castle Memorial Hospital et al.*, Civil No. 4998 (1st Cir., Hawaii, May 24, 1972).
2. In separate dissenting opinions, one judge held that a medical license should be deemed sufficient qualification for privileges, and another felt that either licensure or board certification in a specialty should be prima facie qualification.
3. Cf. Article VIII of the JCAH *Guidelines for the Formulation of Medical Staff Bylaws, Rules and Regulations—1971,* for both departmentalized and nondepartmentalized hospitals.
4. A well-established principle in administrative law that nevertheless permits "judicial notice" of certain commonly recognized facts and principles that require no proof.
5. See *Woodbury v. McKinnon,* 477 F. 2d 839, 844 (5th C.A., 1971), in which the court held as to an informal hearing on privileges: "The plaintiff's [physician's] attorney, although present, was not permitted to question the other doctors present. However, the plaintiff was allowed to ask questions and exercised that privilege freely. Since the attorney and the plaintiff could confer at will, we see no due process violation in the refusal to permit the attorney to ask questions."
6. Cf. Article VII, section 5, paragraph j. of the JCAH *Guidelines for the Formulation of Medical Staff Bylaws, Rules and Regulations—1971,* for both departmentalized and nondepartmentalized hospitals.
7. Ludlan, J.E. Physician-hospital relations: the role of staff privileges. *Law and Contemporary Problems* (Durham, N.C.: Duke University School of Law, Autumn 1970), pp. 879, 889.

The Hospital Staff, 18, 22 (September 1972). Reprinted by permission.

Due Process—From a Practicing Physician's Viewpoint

In the September 1972 issue of The Hospital Medical Staff, *a column was devoted to a discussion of "Due Process in Hearings on Staff Privileges"—an examination of the case* Silver v. Castle Memorial Hospital et al., *497 P. 2d 564 (Hawaii 1972). The following letter from J. A. Fabro, M.D., is printed in response to that column.*

Jay H. Hedgepeth, esq., in writing about "Due Process in Hearings on Staff Privileges," discusses the recent case of *Silver v. Castle Memorial Hospital* from his viewpoint as general counsel and director of the Office of Legal Affairs, American Hospital Association.

I would like to discuss the case as a practicing physician who is interested in this problem, mainly from an ethical viewpoint. Whatever is quoted here from the opinions of the judges mirrors, in my opinion, our American tradition of fair play (ethics) as reflected in the law.

Hawaii has joined the growing list of states who hold that actions of voluntary, charitable, "private" hospitals are subject to judicial review. (The others are California, New Hampshire, New Jersey, Ohio, and Vermont.) Hardly ever do the judges in these cases involve themselves with the substantive issues; rather, they are concerned with procedure, with due process. They ask, "Did the hospital give the physician a fair hearing?" Almost universally, the answer has been "No." The decision of the Hawaii court in this case was unanimous: Dr. Silver was not accorded a fair hearing.

As is usual, the lay hospital board acted on recommendation of the medical accreditation committee, and in principle, they *should* do so, especially in assessing competence. However, they also should know what fair play is. Americans believe that every person is entitled to his day in court, no matter how obnoxious or incompetent he may be.

The physician in question was granted one year's probation, but, according to the case report, "prior to termination of [his] privileges, [he] was never provided with specific written charges as to why his performance was not deemed acceptable." My fairly extensive study of the problem emphasizes the reluctance of most boards to give a defendant physician specific written charges to assist him in preparing a defense. This is the single greatest omission in such cases.

In holding that the physician had not been granted due process, the state court declared that the board had predetermined his guilt before giving him a hearing. The court said that the board " . . . must not be tainted by its own premature decisions prior to the hearing."

A 'Kangaroo court?'

In the last paragraph of the case report, one of the concurring judges states: "I am satisfied from reading the entire record that Castle Memorial Hospital subjected Dr. Silver to a . . . 'kangaroo court,' called at the eleventh hour in an effort to comply with the hospital's own by-laws and to rationalize a result which the board . . . had already reached. Such proceedings are constitutionally intolerable." Not only unconstitutional, but unethical!

Mr. Hedgepeth suggests that a medical staff or governing board faced with the possibility of a charge of prejudgment, bias, or prejudice may do well to consult with the hospital's attorney, who in turn "may wish to consult such authorities as 39 A.L.R. 1476 and 97 A.L.R. 2d 1210, 1222." I suggest that the most complete and recent reference is 37 A.L.R. 3d 637. This reference does not deal specifically with prejudgment, bias, or prejudice on the part of a hospital governing board, but it gives broad and interesting treatment to "exclusion of or discrimination against physician or surgeon by hospital," including special treatment of procedural matters under Section 2 [b].

Advice to the board

I have learned a caveat that should be remembered when consulting an attorney—by nature of his training, he is an advocate of whatever side he is asked to represent. Therefore, I suggest that a board should instruct an attorney as follows: "We want your legal help. But even more, help us to give the physician a fair hearing. We don't want the highest court in the state to say that we have acted like a 'kanagaroo court.'"

I assume that every hospital governing board has reviewed the JCAH *Guidelines for the Formulation of Medical Staff Bylaws, Rules and Regulations, 1971,* especially the section on due process. Finally, I suggest that lay boards read the cases cited below; they are short, not too technical, and demonstrate the trend in the law.

Silver v. Castle Memorial Hospital et al., 497 P. 2d 564 (Hawaii 1972).

Greisman v. Newcomb Hospital, 40 N.J. 389, 192 A. 2d 817 (1963).

Davidson v. Youngstown Hospital Association, 19 Ohio App. 2d 246, 250 N. E. 2d (1969).

Woodard v. Porter Hospital, Inc., 125 Vt. 419, 217 A. 37 (1966).

Willis v. Santa Ana Community Hospital Association, 58 Cal. 2d 806, 26 Cal. Rptr. 640, 376 P. 2d 568 (1962).

—*J. Alfred Fabro, M.D., Torrington, Conn.*

The Hospital Medical Staff 30, 32, (March 1973). Reprinted by permission.

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Information Exchange about Physicians

At the annual meeting of 1974 (A-74) resolution 41 requested the American Medical Association to take immediate action, "in conjunction with component medical societies and the American Hospital Association, to develop legally approved methods whereby information concerning a physician's hospital privileges or practice can be legally exchanged with immunity among all such parties." The House of Delegates referred the resolution to the Board of Trustees for study and report at the Clinical Convention. The Board of Trustees has studied Resolution 41 and submits the following report.

Background

Their resolution addresses a problem that has been of concern to the medical profession and hospitals for some time. Derogatory information concerning a physician's professional performance or conduct that becomes known to peer review and disciplinary committees in hospitals and medical societies frequently has not been released in response to inquiries from other hospitals or medical societies because of an apparent fear that the physician in question might institute litigation against the hospital and its medical staff or the medical society alleging damage to his professional reputation. In some instances, the reluctance to release such information enables an incompetent or unethical physician to move from one hospital to another and from one state to another leaving behind a trail of botched cases or complaints without disciplinary action having been instituted or his license suspended or revoked in any of the settings in which he practiced.

Their resolution seeks to prevent the occurrence of such situations by the development of "legally approved methods" that will provide immunity to those who release information that may affect a physician's professional reputation. The hesitancy to release such information is not based upon reports of judicially assessed liability against hospitals and their medical staffs or medical societies, however, since no reports of successful litigation in this area were found. Publication of the truth may not be welcome, but it does not serve as the basis for successful litigation against the one who releases it. Even the release of erroneous information in the absence of malice or gross negligence does not give rise to a cause of action for which a court will grant relief.

If the fear of exposure to litigation in any way impedes the effectiveness of medicine's efforts to police itself and protect the public from incompetent or unethical physicians, however, a mechanism should be found to assure physicians of protection when responding to requests from hospitals or medical societies. The development of "legally approved methods" to permit the exchange of information concerning a physician's professional performance and conduct "with immunity" assumes that there is some definitive existing legal authority. Such a body of law does not exist in the United States even though formal mechanisms for reviewing and evaluating the professional performance of physicians and instituting disciplinary measures against physicians have been established and implemented by the medical profession for more than a century. The following mechanisms are in current use and, although none of them have been tested in the courts, may provide guidance for hospital medical staffs and medical societies concerned with problems relating to the release of derogatory information about their members.

Consent and Release Forms

The Guidelines for the Formulation of Medical Staff Bylaws, Rules and Regulations - 1971 developed and published by the Joint Commission on Accreditation of Hospitals contains the following suggested bylaw provision:

> "By applying for appointment to the medical staff, each applicant thereby signifies his willingness to appear for interviews in regard to his application, authorizes the hospital to consult with members of medical staffs of other hospitals with which the applicant has been associated and with others who may have information bearing on his competence, character and ethical qualifications, consents to the hospital's inspection of all records and documents that may be material to an evaluation of his professional qualifications for staff membership, releases from any liability all representatives of the hospital and its medical staff for their acts performed in good faith and without malice in connection with evaluating the applicant and his credentials, and releases from any liability all individuals and organizations who provide information to the hospital in good faith and without malice concerning the applicant's competence, ethics, character and other qualifications for staff appointment and clinical privileges, including otherwise privileged or confidential information."

The JCAH suggests that this provision be included in the medical staff bylaws and also on the application form signed by individual applicants for initial and continuing medical staff privileges. Appointment to or continuation of medical staff privileges thus becomes contingent upon the physician's consent to the release by others of information pertaining to his professional competence and conduct and releases from liability those who provide or use such information for evaluating his credentials. The provision included in the Guidelines was based, in part, upon a suggestion made by a Federal District Court in a 1966 suit involving medical staff privileges to the effect that when a physician applies for medical staff privileges, he should make his professional life "an open book" to enable the hospital medical staff to evaluate his competency and his ability to comply with the medical practice standards developed by the medical staff.

The JCAH Guidelines also includes the following Comment under Article XIV, Immunity from Liability:

> "Since the governing body has the overall responsibility for the conduct of the hospital in a manner consonant with the hospital's objective of making available high quality of patient care, and since the organized medical staff has the overall responsibility for the quality of all medical care provided to patients and for the ethical conduct and professional practices of its members, as well as accounting therefore to the governing body, it is of the greatest importance that the most careful consideration be given to appointments and reappointments to the medical staff and to the granting of clinical privileges. In these matters, complete candor is required. Also, every hospital, through its medical staff and management, owes a duty to other hospitals and health care institutions to respond candidly to requests for references and evaluations of practitioners and of other health care personnel practicing, employed, or trained at the hospital."
>
> "However, it is often the case that those charged with performing or contributing to such evaluation and education activities fear that true vigilance may expose them to monetary liability. This fear has adverse consequences upon the entire evaluation and education process. Actually, where they are acting in good faith, without malice, and have made reasonable efforts to ascertain the truthfulness of the information being disclosed or relied upon, the law should, but in some jurisdictions may not, afford protection from civil liability. It is, therefore, important to assure such protection to the fullest extent permitted by law, by clear, unequivocal medical staff bylaw provisions."

The JCAH includes application forms for medical staff privileges and forms for handling inter- and intra-hospital requests for information with a physician's signed agreement to release from liability those who furnish the requested information in the TAP Institutes Manual.

The California Medical Association publication entitled "Guiding Principles for Physician Hospital Relationships" contains the California Medical Association—California Hospital Association Model Medical Staff Application which has a consent and release form for an applicant to sign containing language similar to that used in the JCAH Guidelines and Forms. The Physicians' Record Company Form B-107 for medical staff privilege applications contains similar consent and release provisions. Some county medical societies also use consent and release provisions in forms developed to enable the societies to collect and furnish biographical and professional information on members and to make the information available to hospitals and medical organizations.

The binding effect of these consents to have information concerning the physician's professional qualifications and character released and to waive certain legal rights has not been judicially determined. Physicians should be aware, however, that the protection afforded by these consent and release forms is subject to the same limitations as the common law or statutorily conferred qualified privilege that protects physicians when serving on or providing information to peer review committees. Peer review committee members and those who communicate information to them are protected in what they say or write if the following conditions are met: the communications must be in good faith and without malice; reasonable care must be exercised to ascertain the truth of the matter communicated; the information must be reported accurately and fairly; and the communication must be made only to others with legitimate interest in the information, that is to other persons or committees involved in evaluation of a physician's credentials or medical care evaluation functions.

Statutory Immunity

Thirty-six states have enacted statutes to provide immunity from liability to members of hospital medical staff and medical society peer review committees. These statutes codify the qualified privilege described above. Seventeen of these statutes also include provisions to protect the records and reports of peer review committees from discovery in professional liability litigation.

The Board of Trustees has been informed that the following statute was enacted in California on September 23, 1974:

> ". . . there shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any person on account of the communication of information in the possession of such person to any hospital, hospital medical staff, professional society, medical or dental school, or professional licensing board, when such communication is intended to aid in the evaluation of the qualifications, fitness or character of a practitioner of the healing arts and does not represent as true any matter not reasonably believed to be true."

Although this statute has not been tested in the courts, its enactment is an expression of public policy favoring protection for the activities of the profession designed to improve professional standards and assure access to competent physicians for all members of the public.

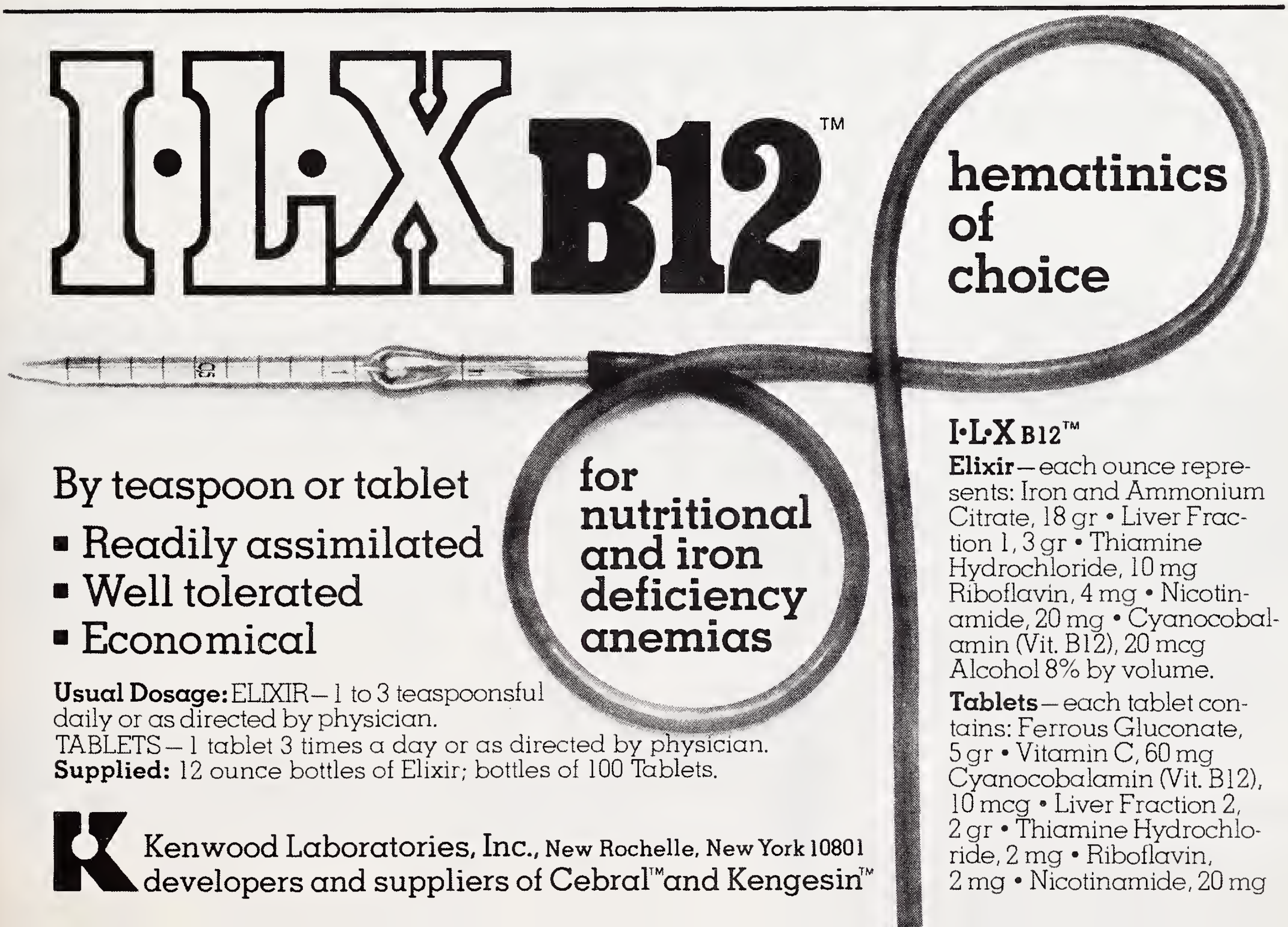
Insurance Protection

Insurance coverage to provide protection against the infrequent and usually unsuccessful litigation a physician might institute alleging damage to his professional reputation in the event that a peer review committee's findings are derogatory and become known to other hospitals, medical societies or the public is available at relatively low cost. Such coverage may be obtained by hospitals, medical societies and individual physicians and provides protection against the costs of defense and damages in actions for libel, slander or defamation. The coverage also extends to the physicians when performing peer review functions on hospital medical staff or medical society committees and the publication of the reports or findings of such committees to other hospitals or medical societies.

Conclusion

The Board of Trustees believes that the risk of liability for the release of information relating to a physician's professional competency and character is minimal if the information released is derived from objective, properly performed peer review and disciplinary committee actions. Public policy favors protecting the communication of such information as long as the communications are made without actual malice, are based upon objective evaluations, are reported accurately and fairly and communicated in order to protect the public. Adoption of Resolution 41 (A-74) is not recommended. The intent and goals sought may be achieved by the use of one or more of the mechanisms described briefly in this Report in those areas where the medical and hospital associations believe that their members would be aided in their efforts to make peer review activities more effective and to share and procure the findings with other institutions or medical organizations.

Confidential Physician Exchange Information, Report of the Board of Trustees of the AMA to the House of Delegates, AMA Clinical Convention, Portland, Oregon, Dec. 1974.



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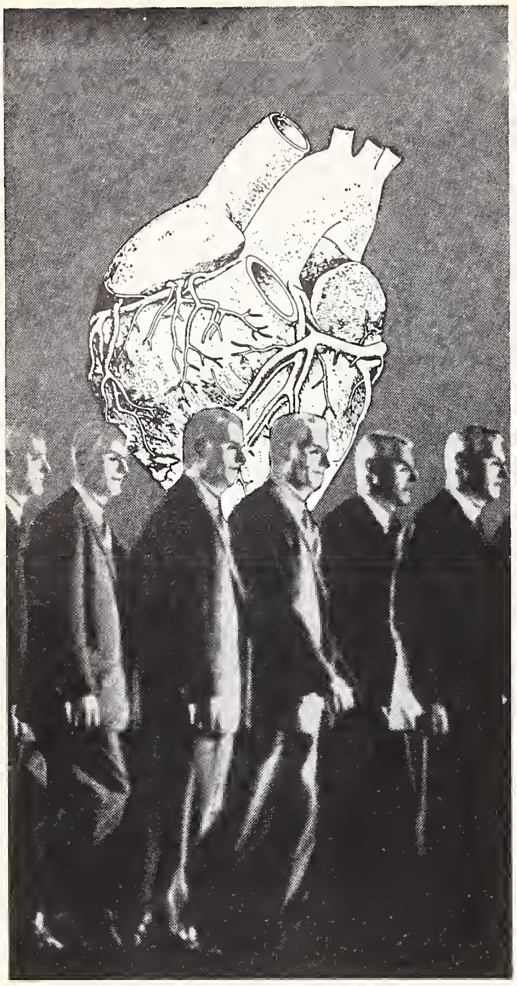

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The Professional Liability Problem

Malcolm C. Todd, M.D.

The problem of professional liability in medical practice is one of great concern, because it has reached crisis proportions in the nation today.

The number of suits, and the dollar awards against doctors and hospitals have risen so high that only a few carriers remain in the business to provide insurance coverage and protection against possible liability.

Malpractice premiums have skyrocketed precipitously. The fact remains, it is our patients—the taxpayers—who pay the bill. $15,000. annual premiums for one to three million dollars protection are passed on to the consumer in the form of higher medical costs since these premiums are a cost of practice that is reflected in the charges for services.

The California Medical Association's testimony and evidence before the Assembly Hearings revealed that in 1968 for every 100 policies issued in that year there were 11.8 claims. Today, there are 25 claims filed for every 100 policies and it is anticipated that this figure will reach 35 suits for every 100 policies issued in 1975. Again, in California in 1969 the average cost of closing such a claim was $5,000. Today this closing cost has doubled to $10,000.

I doubt if we will make appreciable progress in achieving a final resolution of the problem until there is public concern, appreciation, and understanding of the problem, and support for remedial systems to handle malpractice claims. It is an issue that should be of paramount concern to the public. But it must be emphasized that every bad result is not necessarily the result of negligence. Until public concern is evident, we must attempt to provide some alleviation by:

1. Developing programs of education on claims prevention for doctors, nurses, orderlies, and all hospital attendants.
2. Promoting enactment of legislation at the state level to correct some of the inequities that exist today; seek modification of legislation pertaining to the doctrine of res ipsa loquitur, the doctrine of informed consent; and devise equitable methods to assess damages.
3. Establishing boards to carry out settlement by arbitration.
4. Eliminating duplicate payments in judgments when hospital, surgical and disability costs have been covered by insurance or governmental largesse, while at the same time establishing payment mechanisms for injuries directly resulting from medical negligence, error or omissions.
5. Strengthening and expanding existing programs that determine physician practice patterns, that proper disciplinary action be initiated where substandard performance is discovered, and that restrictions be placed on practice privileges where substandard performance is indicated.
6. Encouraging formulation of a system for adjudicating claims to reduce the time spent in litigation.
7. Promoting enactment of federal legislation to include in all Federal financed health programs, including any National Health Institutes program, an arbitration mechanism to handle professional liability claims.
8. Designating that reappointments to medical staffs each year be contingent upon satisfactory performance of practice and lack of justifiable professional liability claims against a medical staff member.
9. Working closely with the Malpractice Commission to develop a data bank and information center for all professional liability activities.
10. Exercising efforts to attain joint liability protection with hospitals, physicians and other providers.
11. Initiating a comprehensive study to ascertain the approximate total medical costs that result solely from the practice of defensive medicine.
12. The immediate goal is to achieve coverage for all through a Joint Underwriting Association among the carriers with necessary reinsurance or co-insurance with or without Federal assistance in reinsurance.

All these are extremely important and will affect the cost of health care until we resolve the problem of professional liability.

DR. MALCOLM C. TODD, 1974-75 President of the American Medical Association, has been a national figure in American medicine for nearly two decades. Dr. Todd, an eminent general surgeon, medical teacher and national authority on health manpower, has been in solo medical practice in Long Beach, California, since the end of World War II. He became the AMA's 129th President at its 1974 Annual Convention and will serve in that capacity until late June, 1975.

Defending Malpractice Cases

Pitfalls to Avoid

(Second of Two Parts)

James A. Harkins, M.D., J.D., F.C.L.M.

In the first part of this two-part series, the author outlined the technical defenses available to the physician sued in malpractice. In this second part, we shall look to the legal pitfalls into which the uninformed practitioner might fall. These pitfalls may make the defense of a malpractice suit incredibly difficult—if not impossible for the physician's attorney. The chief problems to be dealt with here are the lack of a truly "informed consent," and the statutory loss of the defense of "contributory negligence."

Contributory Negligence

In many jurisdictions, if the plaintiff-patient has been at all contributorily negligent, even though the contributory negligence of such plaintiff-patient be microscopic when compared to the negligence of the defendant-physician, such contributory negligence will serve as an absolute defense to a claim against the defendant-physician.

Recently, our State Legislature passed a bill adopting the doctrine of comparative negligence; that is, the negligence of the plaintiff-patient is compared to the negligence of the defendant-physician and judgement will issue on the basis of this comparison. If the plaintiff-patient is guilty only of a microscopic degree of contributory negligence, then, the judgement will be almost totally against the defendant-physician. If the contributory negligence of the plaintiff-patient is great, i.e., perhaps forty percent as compared to sixty percent on the part of the defendant-physician, then the jury will be instructed that they shall first determine the entire damages done the patient and award an appropriate percentage of such damages.

It is seen then that one of the greatest and most valuable of technical defenses is no longer available to the defendant-physician in Connecticut. This again, is by statute and is construed sharply since "any deviation from the common law (by statute) will be scrupulously and sharply construed."

There are cases, however, wherein the statute will not be applied.

An example of this is where a minor patient is brought to the defendant-physician by the parents or parent of such minor. Here, a leg cast may be applied and the parents warned that the patient should be rechecked because of the possibility of infection ensuing. If the plaintiff-patient's parents do not follow the instructions of the defendant-physician, the courts will rule that the negligence of the parents may not be 'imputed' to the minor. This seems a harsh rule—yet, that is the common law and is still in effect in Connecticut.

Here, it would appear that the defendant-physician is 'trapped,' having no way of protecting himself. Harsh though this rule may be, yet that is the way it is.

Now Let Us Look to the Defense of 'Running of the Statute of Limitations'

In Connecticut the statute of limitations in medical malpractice cases as in other cases of negligence is limited to two years. In the case of a death action, the statute of limitations is one year.

There are exceptions to this rule. The question may be as to when the statute of limitations starts to run.

More and more states, including Connecticut, have construed the statute of limitations in such manner, that it does not start to run until such time as the alleged negligence of the defendant-physician is discovered by the plantiff-patient.

In many other states, the running of the statute of limitations is strictly construed, i.e., the 'discovery' doctrine does not apply. This strict construction of the rule serves as an advantage to the defendant-physician. But, this is not the rule in most states including Connecticut.

This places the physician-defendant in a very precarious position. It may be ten, twelve, fifteen, twenty years during which the defendant-physician is exposed to a negligence action by the plaintiff-patient. Thus, it would appear that many negligent actions can never be written off by the running of the statute of limitations. *Caveat—save your old malpractice insurance policies!*

On the other hand, if the plaintiff-patient is found to be careless or negligent in finding that he has been injured by the alleged negligent act of the defendant-physician then, the two year statute of limitations would apply.

DR. JAMES A. HARKINS is a member of the staff of the William W. Backus Hospital, Norwich, Connecticut and is actively engaged in the practice of medicine and law.

Settlement of a Claim for Injury by the Plaintiff Injured, with the Original Tort-Feasor

In Connecticut, as in most other states, if the plaintiff-patient has settled for the damage done him with the original tort-feasor (wrong doer), then, the defendant-physician, who treated the plaintiff for such injuries, cannot be held liable for malpractice. This theory is based on the concept that "but for" the damage done the plaintiff-patient by the original tort-feasor, such plaintiff-patient would not have been required to see or be treated by the alleged negligent defendant-physician.

The Courts feel that this serves the Public policy—in that, it prevents double recovery and prevents excessive use of the courts.

In the case of Workmen's Compensation, where the defendant-physician has been found negligent, this matter is not yet settled. For here, the law differs from the common law. This again is a case of statutory deviation from the common law being strictly construed.

Informed Consent

Here is the case where the plaintiff-patient's attorney will have a field day. If the dangers, possible complications, and side effects are not explained in the presence of a witness and thereafter signed by the witness and the patient and the physician, there is no informed consent. Certainly, the type of consent signed on admission to a hospital which allows a hospital and physician to perform any procedure on the patient which they deem advisable, is no consent at all. For this is consent obtained under duress.

This is the rule in California and several other states and is rapidly moving toward the East.

It will not be long until the Connecticut plaintiff-patient's attorney looks first to the consent form prior to bringing his case before the court.

This will be a tragedy; needless tragedy; since this case will be brought in battery, i.e., wrongful touching, rather than in negligence. Here, it is only necessary to prove that the doctor-defendant performed a procedure on the patient without obtaining informed consent and a bad result ensued. It is not necessary here to have expert witnesses prove that the defendant-physician was negligent.

However, if "informed consent" is obtained, then it is necessary to prove negligence on the part of the defendant-physician—this will require the presence of testimony of an expert witness (and this is difficult to obtain).

Informed consent is a must. This is true except in the case where a full explanation of all the dangers and side effects of the operation or procedure (including any anesthesia involved) might frighten the patient to such a degree that he or she might refuse a lifesaving operation or procedure.

If this be the case, then consent for the procedure or operation must be still obtained from the patient but it is not required that all of the dangers be explained to the patient, if in the opinion of the defendant-physician, this might lead to death or other tragic circumstances suffered by the plaintiff-patient as a result of the patient being scared away from a sorely needed procedure.

Here, the physician can cover his tracks by writing a note on the plaintiff-patient's chart, that he fears were the dangers explained to the plaintiff-patient, then, such plaintiff-patient might very well refuse the operation or procedure and thereby die or suffer permanent injury. *Caveat—this note must be written before surgery; not after.*

The potential defendant-physician would do well here to doubly protect himself by having another physician or nurse sign such statement in his presence.

In summary, malpractice suits are increasing in number year after year. Further, as the notion of examining consent forms is sweeping eastward, physicians may expect higher and higher premiums for their malpractice insurance. This avalanche effect can only be stopped by team adherence to the warnings set out herein.

Summary

In summary, let me say that the malpractice problem is an ever growing threat to the medical profession. Even those cases which are successfully defended cost the Insurance Carriers great sums of money in legal fees for defense. This results in an increase in premiums charged the physician.

Already, our neighboring state of New York has had such shocking experience with malpractice claims that some specialty groups such as neurosurgery and orthopedic surgery have had their malpractice premiums raised to $41,000 per year. In addition to this, their malpractice carrier has stated flatly that it will no longer sell malpractice insurance after July 1, 1975.

This rise in malpractice premiums has forced some very competent practitioners in these fields to close their offices.

New York State is searching for an alternative to the present method of handling malpractice cases—some solution must be found.

Among the proposals offered is a no-fault malpractice scheme, whereby the injured patient need not prove negligence on the part of the defendant-physician; but rather, such injured party need only prove that injury was suffered, which injury arose out of, and in the course of medical or surgical treatment.

In exchange for this granting of no need to show negligence on the part of the physician, the plaintiff-patient will be required to settle for a fixed amount of damages, fixed by a Workmen's Compensation type schedule of damages.

This would seem to the author to be the only solution to the vexatious malpractice suit problem which threatens the very heart of medical care today.

There would be a resultant saving to the Insurance Carrier by way of legal fees and there would be an end to the six and seven figure verdicts which juries are presently handing down.

This saving would be passed along to the physician (and to the patient), and once more allow the physician to carry malpractice insurance.

Since the Federal Government is now paying about 53 percent of the expenditures for medical care throughout our Nation, it seems that the Congress of the United States should also take an interest in this matter, since it is the patient who ultimately must carry the burden of malpractice insurance costs—such costs being built into the fee charged by the physician, and, in the case of those fees paid by the Federal Government to physicians. this added cost of medical care is paid out of tax dollars by the Federal Government.

There is obviously a need for malpractice claim reform on a National basis, let us hope that it comes soon.

A copy of this summary, sent to your Congressman and Senators may expedite this sorely needed action.

Physician's Duty to Assist Patient In Obtaining Medical Insurance

A physician is under a duty to his patient to use reasonable care to fill out and mail a physician's statement necessary for the patient to obtain a health insurance policy, a Delaware court held. Failure of the physician to properly dispose of the form will render him personally liable for any medical expenses suffered by the patient as a result of his not being medically insured, if it can be shown that the physician's failure to forward the physician's statement was the direct cause of the insurance company's refusal to issue a policy to the patient.

In this case the defendant was an obstetrician who had treated the patient, a pregnant woman, for a kidney infection and anemia. After her discharge from the hospital, she and her husband decided to obtain family health insurance coverage. The defendant was named on the form as having treated the patient's kidney infection; consequently the insurance company sent him a routine form known as an "attending physician's statement," which the physician apparently filed and forgot. The insurance company wrote the patient and declined the application for insurance because the underwriting statement had not been received. When, prompted by complaints from the patient, the physician finally sent in the form, the patient and her husband had incurred considerable medical expenses for which the insurance company declined to reimburse them.

Their suit charged the defendant with negligence and the court held the patient's complaint stated a good cause of action and refused to dismiss the suit.

Murphy v. Godwin
303 A.2d 668
February 15, 1973

This judicial decision dramatically emphasizes what numerous courts have stated in various jurisdictions on many occasions; namely, that a physician has a legal (as well as a moral and ethical) duty to legitimately assist his patient in procedural matters of a legal nature when only he, as the treating physician, can accomplish certain things that the patient is obliged to do within the civil legal processes.

A Monitoring Strategy for Quality Assurance Programs

Samuel B. Webb, Jr., Dr. P.H., Martin C. Robson, M.D., and Arthur L. Lanckton, M.P.H.

Introduction

Organized programs for peer review of the quality of all institutional medical care paid for by the federal government is now required by Public Law 92-603.[1] This is the first legislated attempt at formalizing efforts to assess the end results of medical treatment that began as early as 1914 under the leadership of Ernest A. Codman, M.D., chairman of the Committee on Standardization of Hospitals of the Clinical Congress of Surgeons in North America.[2] Later professional efforts in the direction of medical audit were formalized in 1918 by the American College of Surgeons (ACS), including the regular review and analysis of clinical work performed in the hospital. In addition, through individual attention by physicians such as Ward and Ponton, the present concept of the medical audit to assess professional performance was formed.[3] [4] Codman's leadership asked the question, "Why?" Why is a patient managed in a particular way, and what was that patient's outcome? The experience of the ACS, Ward, and Ponton taught us that the medical audit must contain five main features: 1) the criteria used for evaluation must be specific and valid; 2) the criteria must be inclusive to cover all significant aspects of patient care and not just the non-controversial aspects; 3) the medical audit must be done on a continuing, not episodic, basis; 4) the method must be simple and inexpensive; and 5) the audit must be used to benefit the patient and educate, not punish, the physician, for the purpose of improving performance in the future and thus improving patient care.

Interestingly, today as in 1914, there is no one specific standard form of medical audit. Clearly, the passage of Public Law 92-603 will affect the status of medical audits. Because of this, it is believed that physicians will want to know what essentials are needed to make the medical audit an effective monitoring device, thereby having a maximum professional input to that which is legislated but by no means fully developed.

Purpose

The purpose of this paper is to acquaint physicians with existing medical audit systems, review basic essentials necessary for a productive medical audit, and finally, to propose a monitoring strategy for any quality assurance (medical audit) program.

Existing Medical Audit Systems

Extant systems in use really serve only to provide data with which the quality of care in an institution or program can be somehow appraised. For instance, individual hospitals that participate in a discharge abstract data processing system not only compare their data with those of other hospitals but also evaluate, in some manner and in varying degrees, the extent to which they find their data representative of acceptable medical practice. These evaluations take various forms and are not necessarily limited to the data provided by the discharge abstract program. They might include such evaluative activities as tissue committee reviews, review of all hospital fatalities, in-depth study of cases selected at random, clinico-pathological conferences on complex cases of special interest, etc.

PAS—The primary example of such a system is the Professional Activity Study (PAS) developed in 1953. This was the first major data processing system for medical care appraisal based on hospital discharge abstracts. The data base includes patient identification, social characteristics, diagnoses, operation, selected admission findings, investigation (total work-up), management (therapy), and some optional data. Of the independent non-profit systems, PAS is the largest and the only system that is national in scope. As of 1970, subscribing members included 1,300 hospitals in 46 states and Canada, accounting for approximately 30 percent of the discharges from short-term hospitals in the two countries.

MAP—More than half of these hospitals also participate in the CPHA Medical Audit Program (MAP) which was added in 1959 specifically to assist in evaluating quality of care. The MAP expansion provided for more clinical data in-put but did not extend into the area of criteria or standards.

BURP—A number of regional data processing systems based on hospital discharge abstracts have been developed since 1953.[5] One of these, the Connecticut Utilization and Patient Information System (CUPIS), had, as one of its components, the Basic

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Utilization Review Program (BURP). Designed to improve the patient care evaluation process, this program selects cases, based on explicit criteria, that have a high probability of requiring review and then evaluating these cases to determine the appropriateness of services as a measure of the quality of care, appropriateness of admission, and timeliness of discharge. The hypothesis for this approach is that patients in a given diagnostic category that have the same characteristics should therefore exhibit the same patterns of care. BURP concentrated on 34 diagnostic categories that account for a large part of the hospital population. Deviant cases, as measured by length of stay and dollar volume of special services, were considered appropriate candidates for individual evaluation by the medical staff.

While this is a giant step in the direction of converting a data gathering system into an effective quality monitoring system, it does not go so far as to identify and evaluate the performance of individual physicians with respect to the selected criteria. In any event, however, this is the first instance where medical criteria are applied to a major data processing system, so that the system itself identifies cases that fail to meet predetermined objective and explicit criteria. This allows the medical staff to focus its evaluation efforts on only the deviant cases. Unfortunately, the operation of the CUPIS-BURP system was discontinued in early 1973 due to lack of funds.

Others—There are a number of other data processing systems based upon the discharge abstract.[6] Data from these organized systems tend to focus on utilization but, to some extent, also provide information that can be useful to individual hospitals in connection with evaluations of the quality of patient care. They are useful mainly in providing a means for a hospital to compare certain indicators of care experienced in its activities with the same indicators in other hospitals. Typical indicators are length of stay (by diagnosis and age group), social characteristics of patients, principal diagnoses and surgical procedures, death rates, autopsy rates, number of consultations, discharge status and destination (including type of death and autopsy). The main point is, however, that none of the aforementioned systems, except the now defunct CUPIS-BURP, contain any explicit criteria of care. Therefore, they cannot in themselves measure, in any direct sense, the quality of care provided.

Essential Components of a Medical Audit Program

The purpose of any medical audit program is clearly two-fold: 1) to aid the physician in continuing study and improvement of the quality of medical care, and 2) to guarantee that minimal standards are met. Accordingly, Griffith emphasizes that a quality assurance system should include at least the following components:

1. A fact-finding system which identifies quality problem areas.
2. A system of impersonal analysis of facts conducted by skilled physicians.
3. An educational system which spreads the conclusions from the analysis to individual physicians and the staff as a whole.
4. A continuing fact-finding system which monitors achievements of the system as a whole for the staff and for the trustees, to assure that it continues to function effectively in meeting both goals.[7]

Based on his work in Rochester, Lembcke recommends the following for scientific medical audit:

1. Individual case analysis, by specific disease or operation, using explicit, objective criteria.
2. Community-wide epidemiologic data to independently check the results obtained by case analysis.
3. Comparative analysis to determine the accuracy of tissue, laboratory, and radiologic examinations.[8] [9]

Finally, Williams states simply that the basic elements of quality control are:

1. A system for establishing professional standards.
2. A system of surveillance.
3. A system of enforcement.[10]

Lembcke's last two "essentials" go beyond the scope of any internal system as does Griffith's fourth point regarding "a fact-finding system which monitors achievements of the system as a whole."[7-9] In our opinion, Williams' third point—"a system of enforcement"[10]—should result from the self-discipline of the individual physician once he has the insights that a medical audit (quality assurance) program can provide him. In an area as complex as medical care, a program based on imposed enforcement may not lead to improved medical care as effectively as one which aids the physician in his own efforts to improve his performance by pinpointing for the individual those areas needing improvement. This viewpoint underlies much of the impressive work of Williamson, which calls for the routine assessment of both diagnostic and therapeutic outcome rather than the related process variables.[11-15] The key question is whether physicians can reach agreement in setting outcome criteria.

A Monitoring Strategy

To make meaningful use of the existing myriad monitoring systems based on discharge abstract data and the aforementioned essential components of a medical audit or quality assurance program, there must be a fundamental strategy for monitoring and evaluating the quality of patient care provided by physicians. One such strategy that would seem to offer promise of both efficiency and effectiveness is, for convenience, labeled TOPMMAP—an acronym for Triage of Outcome and Process Measures for Medical Audit Programs. The six steps in our TOPMMAP strategy are as follows:

1. Designated representatives of the medical staff to select the diagnoses and operative procedures to be evaluated.

2. Minimum acceptable clinical criteria, expressed as either outcome or process measures, to be agreed upon by the medical staff representatives (and, if felt necessary, by all the physicians whose performance is to be monitored).

3. Actual performance then to be monitored with respect to these criteria. In an on-going system, this can be done either through systematic review of current medical records—with or without the use of data processing methods. It is important to note that this step can be done by non-physicians with a modest amount of training.

4. The data then to be compiled and arranged to show the degree to which the agreed standards have been met by the physicians as a group and individually.

The identity of the individual physician would, of course, be kept confidential and his performance "score" would be used only in ways of which he approved and which would provide him with the maximum benefit in his efforts to improve his own performance. The patient population involved can also be segmented by selected characteristics to determine whether physician performance varies in accordance with different types of patients.

5. The designated physician representatives to review the results and the data to be disseminated in formats designed for maximum educational effect.

6. Either the criteria to be revised in the light of the results obtained or steps taken to remedy performance that fails to meet the agreed criteria.

It must be stressed that the purpose of such a monitoring mechanism is not to be critical or judgmental. Rather, its primary purpose is to identify elements of care that need more careful attention. It also must be stressed that interpretation of the data compiled is the sole responsibility of the medical staff. Finally, low scores in meeting the criteria might be explained in the following alternative ways:

a. The criteria used were inappropriate.

b. The medical record or abstract does not reflect what actually occurred.

c. The criteria do reflect an area where care should be improved.

Action taken in response to any of these three explanations can lead to improved quality of care.

The TOPMMAP monitoring strategy can convert the customary discharge abstract data processing system into an efficient and effective quality assurance program. *If* the medical staff can agree on the criteria to be applied to the diagnostic categories to be evaluated, the system can be programmed to identify only those cases for which the data indicates failure to meet the pre-set standard criteria. Thus, the attention of the professional audit team is concentrated only on the situations that need attention, thereby saving valuable time. The input data should provide for identification of the physicians involved in every case. Thus, those directly concerned can personally benefit from the review of the non-standard case.

As experience is gained with the TOPMMAP strategy, the criteria can be refined progressively. Initially, the medical staff can agree on minimum acceptable standards, the first goal being to ensure that physician performance meets at least these minimum standards. As this is achieved and as the area of agreement can be broadened in the direction of criteria representing optimal care, the standards can be raised progressively toward this optimal level.

Initially, the TOPMMAP strategy can be applied to those diagnostic categories or operative procedures for which agreement as to minimum acceptable standards can be reached most readily. As experience is gained and confidence in the strategy grows, the system can be broadened to cover more diagnostic categories and operative procedures.

Summary and Conclusions

As can be seen readily, the essential concepts exemplified in the TOPMMAP strategy for a quality assurance medical audit program have been advocated by others as mentioned earlier. Specifically, this strategy embodies the first three components outlined by Griffith,[7] the first component of Lembcke,[8 9] the first two components of Williams,[10] as well as Williamson's philosophy concerning quality assurance programs.[11-15] Finally, this strategy formalizes the earliest thinking on the medical audit begun in 1914 by Codman.[2] Moreover, rather than creating yet another new system of discharge data abstracts, it is flexible enough to be incorporated into existing systems.

The one stumbling block is that the underpinning of the proposed TOPMMAP strategy is that established, objective criteria that are age, sex, and diagnosis specific, must be developed and agreed upon by physicians. There is no question that this will be a time-consuming task. However, already physicians are devoting considerable time to one form or another of medical audit activities. With the passage of PL 92-603, such time will, if anything, be increased not shortened. Thus, the increasingly important question is how can this time be spent most effectively in terms of identifying and correcting practices that physicians themselves consider unacceptable? It is believed that the proposed TOPMMAP strategy is one viable alternative.

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Home Care—An Effective Alternative

Frances W. Adams, R.N.

Home Care is an efficient, effective method of coordinating the delivery of high quality hospital-type services to the patient in his own home under the supervision of his private physician. It has been widely accepted that selected patients can benefit from the psychological advantages of their home environment while recuperating from an illness or a surgical procedure.

Some of the primary objectives of Home Care are to provide an extension of hospital services into the home of patients who can be discharged earlier, to provide services to patients with terminal illness so that they may remain with their family, to better utilize hospital beds, to reduce the overall cost of medical care and to expedite recovery from illness.

Home Care is centrally administered by a hospital and provides for private physician-directed medical, nursing, social and related services to selected patients at home. The nursing process of assessment and planning of the patient's continuing needs begins with his admission to the acute care facility. Eligibility for Home Care is based on the need for a combination of skilled professional and supportive services in the patient's home. If the Home Care program appears suitable to meeting the patient's needs, the hospital nurse coordinator, then implements the plan and acts as the liaison between the doctor, hospital, Home Health agency and patient.

Cases most likely to prove suitable for Home Care, can be selected from a wide cross-section of diagnoses and age groups including post-surgery, post-fracture, recovering coronary, strokes, terminal illness, selected chronic disease patients and other types of cases in which hospital care can be replaced by Home Care.

The services usually available to patients on Home Care are Nursing, Physical Therapy, Occupational and Speech Therapy, Home Health Aide, Homemaker, Drugs, Medical & Surgical Supplies, Medical Equipment, IPPB & Oxygen equipment, Transportation, etc. The above are provided only on the recommendation of the patient's physician. To avoid duplication Home Care utilizes the services provided by the local Certified Home Health Agency.

The provision of Home Care services is governed by the patient's health needs rather than by the scope of insurance coverage or any other consideration. From a financial point of view, Medicare and Medicaid will pay for Home Care services as long as the patient meets the eligibility criteria. In hospitals having official Blue Cross Home Care programs, Blue Cross will pay for Home Care services to patients under 65 yrs. of age who require Home Care. Many commercial insurance companies pay for a portion of the above mentioned services although they do not refer to them formally as Home Care.

Presently in Connecticut there are 20 hospital-based Home Care Programs. Several other hospitals have a nurse functioning in a discharge planning role.

Home Care Programs—Hospital based in Connecticut:

1. Bradley - Southington
2. Bridgeport
3. Bristol
4. Charlotte Hungerford - Torrington
5. Day Kimble - Putman
6. Greenwich
7. Hartford
8. Manchester
9. Meriden - Wallingford
10. Middlesex
11. New Britain
12. Norwalk
13. Park City - Bridgeport
14. Rockville
15. St. Mary's - Waterbury
16. St. Raphael's - New Haven
17. St. Vincent's - Bridgeport
18. UConn - McCook - Hartford
19. World War II - Meriden
20. Yale New Haven

On a statewide basis, several professional groups are exploring Home Care from the State Medical Society to the CHA sponsored Continuing Care Coordinators Conference and Council on Continuing Health Care and Connecticut Nurses Association. JCAH has published standards for Hospital-based Home Care programs and is beginning to survey them. With the increased emphasis on ambulatory care and less expensive alternatives in the delivery of Health Care, Home Care is just in its infancy stage in Connecticut.

FRANCES W. ADAMS, R.N., Home Care Coordinator, New Britain General Hospital, New Britain.

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Report to the Council
Committee on Statewide Medical Planning

Deficiencies in the Delivery of Health Care in Connecticut
and
Health Education

Foreword

There is much space devoted by the news media on the difficulties patients have in obtaining medical care. For several years there has been a fear that there will not be enough doctors. Areas without physicians are given widespread publicity. "Crisis medicine" is deplored by planners who advocate HMOs. These expressions of dissatisfaction create two questions. First, do crisis conditions actually exist and, secondly, are steps being taken to correct them?

The Council in its endeavor to answer these questions requested the Committee on Statewide Medical Planning to investigate the deficiencies of delivery of health care in Connecticut and make a report. The Committee discussed the matter at several meetings, took into consideration published articles on the subject in general, and received the ideas of the heads of several Comprehensive Health Planning "B" Agencies. With this background the following report has been prepared.

I. Accessibility of Medical Care
Physician Shortages; Primary Care

There is no denying the fact that there are some deficiencies in the distribution and accessibility of medical care. An analysis of the reasons for these deficiencies brings out several sides to the problem. Primary care physicians—internists, pediatricians and, especially, family practitioners—are needed in greater numbers in certain areas of Connecticut. This need relates not only to current shortages but also to anticipated further shortages that will be created by retirements among those now practicing. For example, the average age of practicing family physicians is approaching that of retirement, and it is evident that a continuing influx of younger doctors trained in family medicine will be necessary if an acceptable population-physician ratio is to be achieved and maintained in communities in which family practitioners are called upon to provide the bulk of primary care.

In some cases, the shortage/distribution problem may be due to the several considerations which prompt a doctor (and spouse and family) to choose one community area in which to set up practice over a number of others. These considerations may be predicated upon such factors as the physician's background and life style, education, training, hobbies, cultural pursuits and a desire to live and work in an environment favorable to both personal and professional interests.

Type of practice also exerts substantial influence on the selection of a practice site. By its very nature, specialized practice requires a potential patient population of sufficient size to assure an adequate patient load, and, in most cases, the availability of a hospital having suitable facilities and services. Hence, even with primary care physicians in internal medicine and pediatrics, specialists in fields other than family medicine tend to locate in urban and large suburban areas. As a consequence, one finds that primary care in smaller communities is apt to be provided in major degree by family practitioners.

Finally, a somewhat less obvious factor that may have been contributing to the shortage of practicing physicians over the past several decades has been the tendency for many medical school graduates to enter fields other than that of patient care. Indeed, it is understood that a significant number of these set out to acquire their M.D. degrees with the overt objective of going into research or pursuing medically-related careers devoid of direct contact with patients. It is possible that the taproot of this special problem may lie with the system of selectivity used by medical school admissions committees. By favoring the admission of candidates who have superior qualifications primarily from an academic standpoint, they may not only tend to pass over the highly motivated, service-oriented student but also tend to unduly narrow their selections to the scientifically-oriented group whose interests can be expected to lead them into research or narrowly specialized endeavors.

Hence, since it appears that the medical manpower needs of smaller communities can best be met by the training of greater numbers of family practitioners, and that the present admissions policies of medical schools may be serving as a deterrent to the achievement of that objective, the Society would be advised to suggest a review of the prevailing candidate selection process to the deans of Connecticut's two medical schools for their opinion as to the possibility of making some modifications thereof.

On the plus side of the ledger, there is a developing movement among today's medical school graduates to enter the field of primary care, in particular the field of family medicine. The exact proportion of such graduates is not known for all schools nor how many of them will ultimately fulfill their intent after a period of postgraduate training is even less well documented. The trend is being supported by many schools via courses directed toward primary care and the establishment of family practice residencies in their affiliated hospitals. Our state is fortunate in that the University of Connecticut Medical School is now committed to promoting family medicine as a field of study and eventual practice.

Whether the recent change in the format of postgraduate training, which eliminates internships and commits the graduate physician to a course of specialized training for a period of several years, will have an adverse effect on the production of family practitioners remains to be seen. However, assuming that primary care residencies in internal medicine and pediatrics are continued as in the past, the Society should encourage attempts to interest students in family practice as a career of comparable attractiveness and professional satisfaction and emphasize the statistical fact that the need for more physicians is most acute in the field of family medicine at this time.

Also, the Society would do well to exert influence to assure that residency programs in family medicine are continued and expanded, especially in Connecticut hospitals, since it seems likely that a number of the residents graduating from such programs would elect to establish practices in the local community areas.

RECOMMENDATION NO. I

(a) That the Society urge the medical schools of the State to consider placing greater emphasis on the recruitment for admission of students indicating an interest in providing direct patient care, especially in the field of family practice, and to encourage students to direct their studies toward the practice of family medicine. (Refer for implementation to the Committee on Cooperation with the Medical Schools of Connecticut).

(b) That the Society urge the hospitals in the State to provide postgraduate education and training in the practice of family medicine. (Refer for implementation to the Committee on Hospitals).

II. Availability of Medical Care—Ghetto Areas

There is substantial evidence to indicate that shortages of privately practicing physicians are likely to be more acute in the so-called "ghetto" areas of urban communities than in communities having populations with a broader socio-economic mix. While there may be a number of reasons why a physician would not be inclined to establish practice in a ghetto-type setting, it is believed that a major reason for such disinclination may be the facts that (a) a high percentage of potential patients are beneficiaries of Medicaid and related medical assistance programs, and (b) the amounts of the payments allowed by the applicable state or municipal agency for services rendered by physicians are grossly substandard compared to the normal ("usual and customary") charges prevailing generally throughout the state.

It is recalled that when Connecticut's Medicaid program allowed payment of "usual, customary and reasonable charges" during part of the years 1968 and 1969, subject to review and approval by a Medical Advisory Committee of which nominees of the Society constituted a majority of the members, the availability of medical care and the quality of medical services were improved markedly for all Medicaid beneficiaries—including, especially, those residing in urban ghettos. Prior to the initiation of that pilot program, when authorized private physicians' care was *limited* to office and home visits, more than 80% of all medical payments were made to fewer than 200 doctors statewide. At the peak period of the pilot program, the number of physicians (in all branches of medicine) providing *definitive* services to some 125,000 Medicaid eligibles had increased to above the 3,000 level. During the eighteen months' life of the UCR "experiment," over 700,000 services were rendered to these needy and near-needy patients at a total cost of only about 8% of all Medicaid dollars spent on all health services in Connecticut, and within the budget funds allocated.

It appears, then, that one way to increase the availability of medical care to ghetto residents would be for the legislature to reinstitute the highly effective pilot Medicaid program of 1968-69, so unwisely discontinued by the 1969 General Assembly on the rather unconvincing grounds that "it *sounded* too expensive to the voters."

RECOMMENDATION NO. II

That the Society take all appropriate legislative actions during the 1975 session of the Connecticut General Assembly to seek the restoration of the type of Medicaid program that proved so successful during 1968-69. (Refer for implementation to the

Committee on Legislation, in consultation with Orvan W. Hess, New Haven, former Medical Director of the State Welfare Department).

III. Problems of Transportation

Next in importance is transportation, again a civic problem. Patients unable to reach a doctor's office or clinic will not seek care until a crisis forces the issue. Red Cross volunteers driving station wagons to get patients to and from clinics is one method of solving this problem. Of course, ambulance service is available, but its use for routine visits and minor illness creates an abuse of the services which are designed for emergencies.

RECOMMENDATION NO. III

(a) That the Society make aware the governing bodies of municipalities and communities that increased availability of public transportation would provide easier access to medical care to the residents thereof.

(b) That the Society urge local Red Cross and Social Service agencies to organize volunteer transportation systems in areas where lack of such systems constitutes a deficiency in medical care access. (Refer (a) and (b) for implementation to the Committee on Accident Prevention and Emergency Medical Services).

IV. The Management of Emergencies

A corollary of access to care is the availability of the doctor in emergencies. The term emergency in this context has to be defined. Is it a true emergency from the doctor's definition, or is it considered as such from the patient's point of view? In either case, deficiencies in availability do exist and are a source of serious complaint. Lack of availability seems to be a highly local problem. Some communities have sufficient doctors available for covering each other when "off call" so that complaints are few. In other areas doctors seem to have created a situation which leaves the patient to resolve his emergency care by requiring ambulance service to the nearest hospital Emergency Room. The tendency for hospitals to staff Emergency Rooms with full-time physicians may have been a factor in creating the attitude among some physicians that all suspected emergency cases should be treated in this facility. Indeed, there are instances of local physicians signing out to the Emergency Room over the weekend. CSMS should certainly make every effort to head off such a tendency. The poor public relations created by this practice should be publicized to doctors to prevent further erosion of the public's confidence in physician availability.

Looking at emergency care from another point of view, it is obvious from the rise in attendance figures in Emergency Rooms that patients depend on this facility. It has already been pointed out that one reason is the lack of physician availability. Another reason is the anxiety of the patient with insufficient understanding of his problem to make a proper judgement as to the real emergency nature of his medical needs. A further reason is knowledge of the possible serious portent of certain symptoms from publicity about heart attacks and unrecognized fractures, etc. These considerations bring up the question of health education. This is a large subject in itself which will be considered later. It also raises the subject of ambulance service. There are areas where this service is not adequate or is dependent on private ambulances. Some hospitals maintain ambulances; in other areas the police and fire departments provide the service. Again, this is a complex subject and best solved at the local level. Abuse of the service is cause for complaint from the patients as well as those who drive the ambulances. To some degree this is inevitable because not all suspected emergencies prove to be so. Nevertheless, the medical profession should assume the responsibility for seeing that ambulance service is available in the community and that it is used appropriately. Its use should not be restricted only to accidents and emergencies because there is a real need for transportation of invalid cases to and from home, hospital and long term facilities.

RECOMMENDATION NO. IV

(a) That the Society promote, through internal public relations, the need for physicians to meet their obligation to be available or provide adequate "off call" coverage, in emergency situations, to the patients for whom they are responsible.

(b) That the Society publicize appropriately to the membership that signing out to a hospital Emergency Room during absences without prior arrangements with an Emergency Room is poor practice and degrades the quality of medical care in areas where the practice has become customary. (Refer (a) and (b) for implementation to the Committee on Public Relations).

(c) That the Society advocate that ambulance services, being vital to health care, be established in all communities or contiguous community areas by whatever local sponsorship is most suitable; that the ambulance services and their availability should satisfy the needs of the area served; and that ambulance attendants be adequately trained.

(d) That the Society advocate that physicians cooperate in community efforts to assure that ambulance services are not abused in their communities of practice. (Refer (c) and (d) for implementation to the Committee on Accident Prevention and Emergency Medical Services).

V. The Making of House Calls—After Office Hour Care

The matter of house calls naturally stimulates much discussion. This varies considerably due to local custom, specialty, and judgement. It is impossible to establish any rules. The decision must be left to the doctor at the time. However, CSMS could promote the idea that dedication to patient care and some concern for the quality of his own performance, and consideration of the patient's point of view, will, by necessity, occasionally result in a house call being the most expeditious means of rendering medical care. Some doctors deal with these situations by seeing the patient in a hospital Emergency Room or in their offices after regular hours.

RECOMMENDATION NO. V

That the Society bring to the attention of the membership that house calls and after-office-hour care may be essential medical services that should be rendered by physicians when conditions warrant. (Refer for implementation to the Committee on Public Relations).

VI. Home Health Services

Medical care at home needs to be re-emphasized. Some hospitals arrange with Blue Cross for "Home Care" benefits for periods of time after discharge. This has shortened hospital stay and materially improved care. Home care should be promoted to involve all hospitals. Other aspects of care at home are acute, self-limiting conditions (such as URI and childhood diseases), first aid and emergency care, care of the elderly, and long term illnesses. In order for this care to be handled appropriately by patients and their families, a program of education will be necessary. It is recognized that ancillary services including equipment, nursing service, home makers, and physiotherapy are needed at home in varying degrees. This can be organized under a well-coordinated Home Care Program.

RECOMMENDATION NO. VI

That the Society encourage local hospitals to establish Home Care Programs which can expedite the early discharge of patients from the hospital. (Refer for implementation to the Committee on Hospitals).

VII. Extended Care Facilities

Another deficiency in care is in the long term facility (nursing homes, extended care facilities, convalescent hospitals, etc.) Without enumerating examples there must be some method developed to improve the quality of care in many such institutions. Those without a physician designated as the medical director, who can render medical decisions as needed, should be obliged to provide one. If such a medical director is reluctant to advise a physician of his private patient's needs, there should be a review committee or a medical staff available to pass on the quality of care rendered and advise the attending physician if quality of care is not adequate. Such a peer review committee is functioning in many such facilities and CSMS should encourage all of them to create such a body. This committee would establish minimum standards of care and see that these criteria are met. It would be wise to seek the cooperation of the local medical society in selecting the members of such a committee.

RECOMMENDATION NO. VII

(a) That the Society advocate that the medical director of each extended care facility serve as consultant to the administrator for the purpose of assuring a high quality of medical care for all patients in each such facility.

(b) That the Society advocate that each extended care facility select and maintain in operation a peer review committee for the purpose of assuring high quality of the medical care rendered by physicians serving patients in each such facility. (Refer (a) and (b) for implementation to the Committee on Continuing Medical Care and Rehabilitation).

VIII. Health Education for the Public

For the past nine months the Committee has been considering various aspects of health education. The importance of a public educated in health matters is obvious from the foregoing discussion and has been noted in several of the previous paragraphs. The subject has received widespread attention in many fields. The federal government appointed a Committee on Health Education which made a national survey and submitted a report basically advocating a "National Center for Health Education." The AMA promotes education in its sponsored TV programs and lay publications. CSMS has long been interested in health education, especially within the public school system. A separate discussion of health education is appended to this report because it is interwoven with so many aspects of health care.

Education of the patient is a multifaceted subject. Doctors do educate their patients to be able to take better care of their individual needs and diseases. Criticism has been raised that this is not sufficient, so visiting nurses add their advice and practical measures to the educational process. Hospitals have classes for new mothers and are adding classes for diabetic, heart, pulmonary, and colostomy patients. There is no doubt that these supplementary facilities add to the patient's ability to understand and take better care of his disease.

RECOMMENDATION NO. VIII

That the Society encourage hospital medical staffs to establish patient education programs especially directed to the various chronic illnesses and disabilities requiring long term self-care, in cooperation with the hospitals' nursing, dietetic and physical therapy departments. (Refer for implementation to the Committee on Hospitals).

IX. Patient Education (First Aid)

First aid courses are a valuable educational tool for families as well as for ambulance attendants. The only admonition here is not to try to teach too much. There is a limit for what a lay person can be responsible. Knowledge that cannot be assimilated and used properly can become a hindrance.

Another aspect of patient education is in care of other home health needs such as acute illness, and long term care of chronic illness. Granted there are overlapping applications of these phases of education, but much anxiety and overuse of Emergency Rooms can be avoided by some basic medical knowledge of a few common disorders. Better care at home can provide many benefits, one of which would be a financial saving. The hospital insurance carriers would benefit, but ultimately the public itself would be the actual benefactor.

RECOMMENDATION NO. IX

That the Society advocate that first aid courses for the general public be extended and expanded and be made essential for the qualification of ambulance attendants, and that course instruction include nursing care of minor illnesses and common physiological needs (enemas, etc.). Refer for implementation to the Committee on Public Relations).

X. Health Education in Schools

Notwithstanding the importance of the above aspects of health education, the Committee believes the fundamental effort will ultimately have to be directed to the school-aged child. It is further thought that this can best be accomplished through the school system, and that health education be in continuing, progressive increments from kindergarten through high school. Health care is certainly developing more technical aspects requiring sophisticated professional judgement and techniques, but there are common sense principles which the Committee feels the public can well understand with a direct benefit to itself in time, money and anxiety. Starting gradually in the early grades of school and increasing a child's awareness and understanding of simple facts of self care and hygiene will be of sufficient long term benefit to society in a generation to come so as to make the expenditure of much effort and a little actual expense worthwhile.

CSMS is already on record as in favor of a school health education program. The chairman of the Education Committee of the State Legislature Senator (Mrs.) Truex is aware of the need for revision of the state statutes to include health subjects in the curriculum and has indicated that a study and report to the General Assembly will be forthcoming. CSMS should make every effort to cooperate in that study.

Connecticut can be proud of the example set by the City of Hamden which has already a well integrated health education program through all grades in its school system. Since it has been done so successfully in Hamden there is no reason that it cannot be done throughout the state. It will take some real leadership and effort on the part of local doctors, in cooperation with the local school boards, to put such a program into effect. CSMS could provide the guidance, and above all the leadership, in getting the project started. The momentum to keep it going would follow on the success of the program. Dr. Leonard Parente, Hamden, can provide outline and advise.

RECOMMENDATION NO. X

(a) That the Society cooperate with the Committee on Education of the General Assembly to provide a health education curriculum in the school system. (Refer for implementation to the Committee on Legislation).

(b) That the Society advocate to local school boards that health education programs be set up in their respective communities under local leadership and with advice from a local medical society. (Refer for implementation to the Committee on Public Health).

Summary and Conclusions

The Committee is fully aware that the State Society's committee structure includes a number of committees capable of implementing one or more of these various recommendations. It is a fact born of experience that the diversification of such a wide spread program, as described, tends to diffuse the effectiveness and lose its productiveness. Therefore, the Committee would make the suggestion that the Council consider the advisability and feasibility of establishing an additional administrative department to undertake the coordination, detailed supervision, and implementation of this program so that it will not be lost in committees, left to local societies, dealt with by resolution, and die of neglect. Connecticut must be solely responsible for eliminating its own deficiencies in medical care delivery. It should certainly be *responsible* for its own health education to the public. This latter is a movement developing in many areas throughout the country and CSMS should be in the vanguard of this effort.

THE COMMITTEE ON STATEWIDE MEDICAL PLANNING

Frederick C. Weber, Jr., M.D., Chairman

Sidney L. Cramer, M.D.
Jerome K. Freedman, M.D.
Morris A. Granoff, M.D.
David A. Grendon, M.D.
Orvan W. Hess, M.D.
Carl W. Johnson, M.D.
Charles M. Krinsky, M.D.
Leonard Parente, M.D.
Kurt S. Pelz, M.D.
Oliver J. Purnell, M.D.
James H. Root, Jr., M.D.
Hilliard Spitz, M.D.
Andrew F. Turano, M.D.
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Medical Director
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Assistant Medical Director

ELMCREST PSYCHIATRIC INSTITUTE
25 Marlborough Street
PORTLAND, CONNECTICUT 06480
(203) 342-0480

183rd ANNUAL MEETING
# of the
CONNECTICUT STATE MEDICAL SOCIETY
Hartford Hilton Hotel
10 Ford Street, Hartford, Connecticut
April 30, May 1, 1975

COMMITTEE ON PROGRAM OF THE SCIENTIFIC ASSEMBLY

William F. Eckhardt, Jr.

William F. Eckhardt, Jr., New Canaan, Chairman
Michael J. Esposito, Meriden
D. Norman Markley, Hartford
Malcolm M. Ellison, New London

A MESSAGE FROM THE PRESIDENT

This year the format of the annual meeting has been changed and instead of a three day meeting, as it has been in the past, it will be a two day meeting.

On Wednesday, April 30, the House of Delegates will meet at which time the reports of officers, committees and various resolutions introduced from county associations and individual members will be acted upon. Election of officers and committees for 1975-76 will also take place at this time. Members of the Society, who are not members of the House of Delegates, are welcome to be present at this meeting and participate in the reference committee hearings, where they can make their views known on the business to come before the House.

The annual dinner for all members of the Society and guests will follow the meeting of the House of Delegates. The inauguration and inaugural address of the incoming President, Guy W. Van Syckle, Danbury, will take place at the annual dinner. All members should make every effort to be on hand for this function.

On Thursday, May 1, the scientific program will be held and an excellent program has been arranged, the theme of which is "What You Need To Know About Breast Cancer-1975." Every aspect of this subject will be discussed and should be of interest to all physicians. All of the specialty sections will also meet on Thursday, with one-half of the sections meeting in the morning and one-half in the afternoon.

I urge every member of the Society to take advantage of this excellent opportunity of continuing medical education which is so important today when so many advances are being made in medical technology.

James H. Root, Jr.

GENERAL INFORMATION
READ CAREFULLY

REGISTRATION

The registration desk will be located in the lobby of the hotel and everyone attending the meeting is requested to register. There will be no charge for registration and all members of the Society will be given a guest luncheon ticket when and only if they register.

PARKING

There are ample parking facilities at the hotel and in the surrounding area.

TELEPHONE

Telephone messages will be received at Hartford 249-5611.

LUNCHEON

Luncheon will be served in the Terrace Room on the mezzanine floor on May 1 and ALL MEMBERS OF THE SOCIETY REGISTERING WILL BE THE GUESTS OF THE SOCIETY. PLEASE REMEMBER A LUNCHEON TICKET WILL BE GIVEN TO MEMBERS ONLY IF THEY REGISTER.

HOTEL ACCOMMODATIONS

Persons who wish to remain overnight should make reservations not later than two weeks prior to opening date of the meeting. Reservations will be held until 6:00 P.M. on the day of arrival, unless later hour is specified. Please indicate in your letter that you are attending the Connecticut State Medical Society meeting. Your letter should be directed to the Front Office Manager, Hartford Hilton Hotel, 10 Ford Street, Hartford, Connecticut.

ANNUAL DINNER

The Annual Dinner will be held at the hotel on Wednesday, April 30, 1975. The social hour will be at 6:30 P.M. and the dinner at 7:30 P.M. All persons attending the dinner will be the guests of the Society at the social hour. Your reservations for dinner should be sent in as soon as possible to the CSMS office.

PROGRAM

The scientific portion of the Annual Meeting will be concentrated in one day, May 1, 1975. The general program will be held in the Capitol Ballroom between 10:30 and 4:30; and section meetings will be held in the morning at 8:30 A.M. and in the afternoon at 4:30 P.M. in the rooms listed in the program.

EXHIBITS

All the exhibits will be located on the mezzanine floor. Physicians should take advantage of the opportunity to review what is new and timely by visiting the commercial exhibits.

ALL ACTIVITIES WILL TAKE PLACE AT THE HOTEL UNLESS OTHERWISE INDICATED.

CONTINUING MEDICAL EDUCATION CREDITS

AMA PHYSICIAN'S RECOGNITION AWARD

The Yale University School of Medicine has accredited the scientific program of the Society's Annual Meeting for Category One Credit toward the AMA Physician's Recognition Award. Credit is granted in this category on an hour-for-hour basis.

AMERICAN ACADEMY OF FAMILY PHYSICIANS

The Commission on Education of the AAFP has accredited the scientific program of the Society's Annual Meeting for 5-1/2 hours of prescribed credit for the general lectures and the family practice section meeting, and one hour for elective credit for each lecture attended which is presented by the individual specialty sections of the Society.

HOSPITAL RESIDENTS, INTERNS AND MEDICAL STUDENTS ARE CORDIALLY INVITED TO ATTEND THIS MEETING.

ANNUAL MEETING OF THE HOUSE OF DELEGATES

WEDNESDAY, APRIL 30

CAPITOL BALLROOM MEZZANINE

Presiding:
Kenneth F. Brandon, *Hartford, Speaker of the House*
Timothy F. Nolan, *Greenwich, Vice-Speaker of the House*

7:30 REGISTRATION OF DELEGATES
Continental Breakfast for Delegates and Official Guests

8:30 CALL TO ORDER
OPENING SESSION
REFERENCE COMMITTEE HEARINGS

1:15 LUNCHEON—Terrace Room, Mezzanine
FIFTY YEAR MEMBERSHIP AWARDS
Edward Pratt Allen, Orange
Anthony William Battista, New Haven
Theodore Schlosser Evans, New Haven
James Charles Fox, Jr., West Hartford
Lloyd Leslie Maurer, Woodbridge
Owen Lee Murphy, Simsbury
Charles William Nichols, Wellfleet, Mass.
Samuel Burton Rentsch, Derby
Max H. Ruby, Waterbury
Nathan Robert Tolk, Fairfield

3:00 CALL TO ORDER—Capitol Ballroom
FINAL SESSION

6:15 ADJOURNMENT

ANNUAL DINNER OF THE SOCIETY WEDNESDAY, APRIL 30

TERRACE ROOM MEZZANINE
Social Hour 6:30 P.M. Dinner 7:30 P.M.

PROGRAM

Presiding: James H. Root, Jr., *Waterbury*

PRESENTATION OF GUESTS AND DELEGATES FROM STATE MEDICAL SOCIETIES

INAUGURATION OF INCOMING PRESIDENT
GUY WEAVER VAN SYCKLE, DANBURY

PRESIDENT'S ADDRESS

DINNER MUSIC

AUXILIARY TO THE CONNECTICUT STATE MEDICAL SOCIETY

THIRTY-FIRST ANNUAL MEETING
WEDNESDAY, APRIL 30
GOVERNOR'S MANSION
990 Prospect Avenue Hartford, Connecticut

President: Mrs. George E. Roch, *Willimantic*
Recording Secretary: Mrs. Malcolm Edgar, *Norwich*
Corresponding Secretary: Mrs. Raymond Bopp, *Mansfield Center*

12.00 Registration

12:30 Luncheon

2:00 Greetings: The Honorable Ella Grasso, Governor
GUEST SPEAKER: Mrs. Earle E. Wilkinson, Nashville, Tennessee; President-Elect of the AMA Auxiliary
Installation of Officers—1975 - 76

2.30 Business Meeting

Members of the Auxiliary are invited to attend the Annual Dinner of the Connecticut State Medical Society, which will be held at the Hartford Hilton Hotel, beginning with the social hour at 6:30 P.M.

GENERAL SCIENTIFIC PROGRAM
THURSDAY, MAY 1

MORNING SESSION

8:15 **REGISTRATION**—Hotel Lobby

8:30—10:00 **MEETINGS OF SECTIONS OF THE SOCIETY AND GUEST ORGANIZATIONS**
(Listing elsewhere in program)

10:00 **INTERMISSION TO VISIT EXHIBITS**

BALLROOM

10:20 **CALL TO ORDER AND WELCOMING REMARKS**
Guy W. Van Syckle, Danbury, President
Connecticut State Medical Society

SYMPOSIUM: WHAT YOU NEED TO KNOW ABOUT BREAST CANCER, 1975

Symposium Chairman: Ira S. Goldenberg, New Haven, Connecticut, Professor of Surgery, Yale University School of Medicine.

10:30 **INTRODUCTION**—Dr. Goldenberg

WHY DOESN'T EVERY WOMAN GET BREAST CANCER? AND WHAT ABOUT HORMONES?
STANLEY G. KORENMAN, SEPULVEDA, CALIFORNIA: Professor and Vice-Chairman, Department of Medicine, U.C.L.A. San Fernando Valley Medical Program.

HOW TO FIND THE WOMAN WITH BREAST CANCER?
PHILIP R. KARSELL, ROCHESTER, MINNESOTA: Consultant in Diagnostic Radiology, Mayo Clinic and Mayo Foundation; Instructor in Radiology, Mayo Medical School.

HOW MUCH HELP IS THE PATHOLOGIST?
GILBERT H. FRIEDELL, WORCESTER, MASSACHUSETTS: Chief of Pathology, St. Vincent Hospital; Professor of Pathology, University of Massachusetts. Medical School.

12:30 **INTERMISSION TO VISIT EXHIBITS**

1:00 **LUNCHEON**—Terrace Room

AFTERNOON SESSION
BALLROOM

PROGRAM ARRANGED WITH CONNECTICUT SOCIETY OF AMERICAN BOARD SURGEONS

2:00 **SO SHE HAS BREAST CANCER, NOW WHAT?**
Participants:

GEORGE CRILE, JR., CLEVELAND, OHIO: Emeritus Consultant, General Surgery, Cleveland Clinic.

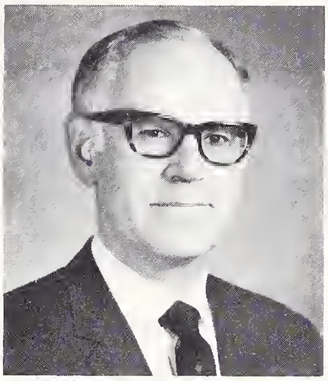
THOMAS J. ANGLEM, BOSTON, MASSACHUSETTS: Associate Clinical Professor of Surgery, Boston University Medical School.

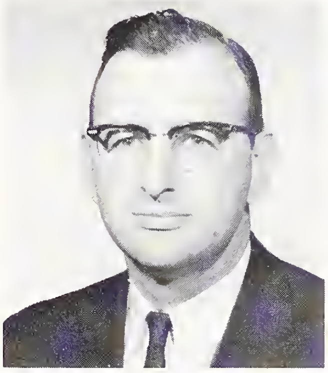
LEONARD R. PROSNITZ, NEW HAVEN, CONNECTICUT; Associate Professor of Therapeutic Radiology, Yale University School of Medicine; Attending Radiotherapist, Yale-New Haven Hospital.

4:00 **INTERMISSION TO VISIT EXHIBITS**

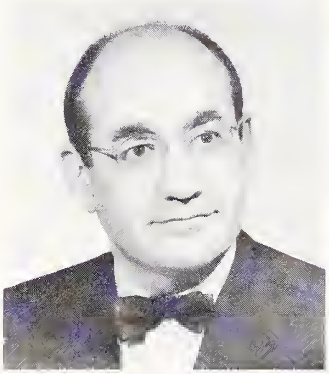
4:30 **MEETINGS OF SECTIONS OF THE SOCIETY AND GUEST ORGANIZATIONS**
(Listing elsewhere in program)

SYMPOSIUM SPEAKERS

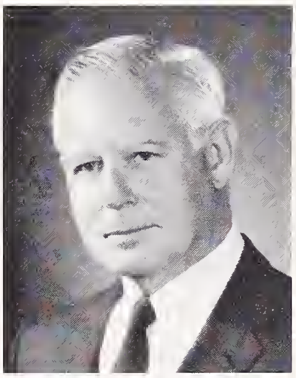

Ira S. Goldenberg


Stanley G. Korenman

Philip R. Karsell


Gilbert H. Friedell

George Crile, Jr.


Thomas J. Anglem

Leonard R. Prosnitz

THURSDAY, MAY 1
MEETINGS OF SECTIONS OF THE SOCIETY AND GUEST ORGANIZATIONS

MORNING SESSION

SECTION ON FAMILY PRACTICE

8:30 A.M. Boston-Buffalo Rooms

President: Edward A. Felder, Norwalk
Secretary: Theodore Safford, Ridgefield

Symposium on Sports Medicine
Duties and Responsibilities of the Team Physician
James Donovan, Hartford

Injuries to the Throwing Shoulder and Hamstrings
William Waskowitz, New Britain

Prevention of Major Sports Injuries
Norman Zlotsky, Rockville

ALL PHYSICIANS INTERESTED IN SPORTS MEDICINE ARE INVITED TO ATTEND.

SECTION ON FORENSIC MEDICINE

8:30 A.M. Room 404

President: Joseph E. Daly, Waterbury
Secretary: Daniel W. Benninghoff, Greenwich

Business Meeting

Scientific Program (See General Program—10:30)

SECTION ON INTERNAL MEDICINE

8:30 A.M. Room 420

President: Walter S. Morgan, New Haven
Secretary: Robert S. Gordon, New Haven

Endocrine Manipulation in Abnormal Breast Cancer
James Streeto, Hartford

SECTION ON PHYSICAL MEDICINE AND REHABILITATION

8:30 A.M. New York-Washington Rooms

President: Kent E. Sharian, Waterbury
Secretary: Manuel Mino, New Britain

Muscles Alive with Biofeedback
John V. Basmajian, Atlanta, Georgia; Professor of Physical Medicine and Rehabilitation, Emory University School of Medicine.

SECTION ON PREVENTIVE MEDICINE

8:30 A.M. Room 424

Chairman and Secretary: J. Howard Johnston, Hartford

Medicine At Its Finest: A Risk Factor Detection and Disease Prevention Approach. (Hypertension, Atherosclerosis and Cancer)
H. Robert Silverstein, Hartford, FACC Chairman, Professional Education, Connecticut Heart Association.

SECTION ON PSYCHIATRY

8:30 A.M. Rooms 436-440

President: James M. Trench, Hartford
Secretary: Darius G. Ornston, Jr., New Haven

Management of Alcoholism in Private Practice—Panel Discussion
Participants:
John H. Sayers, Hartford
Peter R. Manes, Yale University School of Medicine, New Haven
John S. Tamerin, Silver Hill Foundation, New Canaan

SECTION ON PULMONARY DISEASES

8:30 A.M. Rooms 408-412

President: Sreedhar Nair, Norwalk
Secretary: Norman Fine, Derby

Obstructions of Peripheral Airways
Roland H. Ingram, Jr., Boston, Massachusetts; Associate Professor of Medicine, Harvard Medical School; Director, Respiratory Division, Peter Bent Brigham Hospital.

AFTERNOON SECTION PROGRAMS

SECTION ON ALLERGY

4:30 P.M. Room 424

President: Philip I. Weisinger, New Haven
Secretary: Robert Lanzi, Orange

PSRO—A Simplified Explanation of Implementation and Procedures
James D. Kenney, New Haven, Connecticut; Assistant Clinical Professor of Medicine, Yale University School of Medicine.

SECTION ON ANESTHESIA

3:00 P.M.
Hunt Memorial Building
230 Scarborough Street, Hartford, Connecticut

President: Anthony J. Dougherty, Hartford
Secretary: John T. Conroy, Hartford

3:00 Executive Meeting
4:00 Business Meeting
Speaker and Subject to be Announced

SECTION ON NEUROSURGERY

5:30 P.M.
Gelston House, East Haddam, Connecticut

President: Joseph S. Sadowski, Hartford
Secretary: Donald W. Cooper, New London

Speaker and Subject to be Announced

SECTION ON GASTROENTEROLOGY

4:00 P.M.

University of Connecticut School of Medicine
Farmington, Connecticut

President: Robert S. Rosson, Hartford
Secretary: Morton Bender, New Haven

4:00 A WORKSHOP ON E.R.C.P.—PANEL DISCUSSION

Paul Webster, Augusta, Georgia; Chief of Medical Service, VA Hospital, Professor of Medicine, University of Georgia.

Terrence J. Ball, Yale University School of Medicine.

William P. Slover, Jr., Hartford Hospital

Robert S. Rosson, University of Connecticut School of Medicine.

5:30 RECEPTION AND TOUR OF JOHN DEMPSEY HOSPITAL

7:00 DINNER—GUEST SPEAKER—Paul Webster
Subject—"Molecular Gastroenterology"

9:00 ADJOURNMENT

SECTION ON OBSTETRICS AND GYNECOLOGY

4:30 P.M. Boston-Buffalo Rooms

President: Peter A. Goodhue, Stamford
Secretary: Philip Dennen, Waterbury

SEX THERAPY—WHAT IS IT ALL ABOUT?

Alan J. Wabrek, Assistant Professor, Obstetrics and Gynecology, University of Connecticut Medical School and Carolyn J. Wabrek, M.Ed., Co-Directors, Sexual Counseling Program, Hartford Hospital.

SECTION ON OPHTHALMOLOGY

4:30 P.M. Rooms 436-440

President: Frederick D. Williams, Stamford
Secretary: Lewis A. Dalburg, New Britain

SPEAKER AND SUBJECT TO BE ANNOUNCED.

SECTION ON UROLOGY

4:30 P.M. New York-Washington Rooms

President: Richard J. Spillane, Hartford
Secretary: Leo Charendoff, Manchester

SURGICAL MANAGEMENT OF URETHRAL STRICTURES

Leonard Zinman, Boston, Massachusetts; Senior Staff, Department of Urology, Lahey Clinic Foundation.

CONNECTICUT MEDICAL POLITICAL ACTION COMMITTEE (COMPAC)

4:30 P.M. Room 412

Chairman: George E. Roch, Willimantic
Secretary: Mrs. John J. Mendillo, Hamden

BUSINESS MEETING

ELECTION OF OFFICERS

SECTION ON ORTHOPEDICS

2:00 P.M.

DeSales Hall—St. Francis School of Nursing
338 Asylum Avenue (across from Hilton Hotel)
Hartford, Connecticut

President: William H. Fisher, Waterbury
Secretary: Martin L. Karno, New London

TREATMENT AND PREVENTION OF THROMBO-EMBOLIC PHENOMENON INCLUDING FAT EMBOLI

Charles Evarts, Professor and Chairman of Department of Orthopedic Surgery, University of Rochester School of Medicine.

Bimalin Lahiri, St. Francis Hospital, Hartford.

TREATMENT AND PREVENTION OF ORTHOPEDIC INFECTIONS

Carl Norden, Associate Professor of Medicine, University of Pittsburgh.

Peter Dineen, Professor of Surgery, New York Hospital.

5:00 SOCIAL HOUR AND DINNER TO FOLLOW

SECTION ON OTOLARYNGOLOGY

3:30 P.M.

Yankee Silversmith Inn
Wallingford, Connecticut

President: Arthur W. Samuelson, Bridgeport
Secretary: Ronald J. Pimpinella, Torrington

LESIONS OF FACIAL NERVE

Mark May, Pittsburgh, Pennsylvania; Otolaryngologist, University of Pittsburgh.

SECTION ON PATHOLOGY

4:30 P.M. Room 408

President: Michael Kashgarian, New Haven
Secretary: Bertrand P. Bisson, Waterbury

THE PATHOGENESIS AND NOMENCLATURE OF URINARY BLADDER CANCER

Gilbert H. Friedell, Worcester, Massachusetts; Chief of Pathology, St. Vincent Hospital, Professor of Pathology, University of Massachusetts Medical School.

SECTION ON PROCTOLOGY

4:30 P.M. Room 420

President: Bernard J. Kaplan, Hartford
Secretary: Sanford Savin, Bridgeport

NON-OPERATIVE TREATMENT OF HEMORRHOIDS

Fred Mantel, Hartford, Associate Surgeon, Mount Sinai Hospital.

SECTION ON RADIOLOGY

4:30 P.M. Room 416

President: Richard J. Cobb, Hartford
Secretary: Mehdi S. Eslami, Waterbury

BUSINESS MEETING

SECTION ON THORACIC AND CARDIOVASCULAR SURGERY

4:30 P.M. Room 404

President: Joseph P. Shea, Bridgeport
Secretary: Allan L. Toole, New Haven

BUSINESS MEETING

CONNECTICUT SOCIETY OF AMERICAN BOARD SURGEONS

Ballroom

President: James H. Foster, Hartford
Secretary: Raymond K. Bopp, Willimantic
Presiding: Ira S. Goldenberg, New Haven

10:30-4:00 P.M. (SEE GENERAL SCIENTIFIC PROGRAM)

4:15 PRESENTATION OF PAPERS

INCIDENCE OF BREAST CANCER IN CONNECTICUT
Mr. John T. Flannery, Registry Director, Connecticut Tumor Registry.

USE OF AN OUTPATIENT FACILITY AND LOCAL ANESTHESIA IN THE SURGERY OF BENIGN BREAST DISEASE
Phillip E. Trowbridge, Hartford
H. David Crombie, Jr., Hartford

LYMPHANGIOGRAPHIC STUDIES IN OBSTRUCTIVE LYMPHEDEMA OF THE UPPER EXTREMITY
Morton G. Feldman, Bridgeport

THE POSTMASTECTOMY ARM
Guy F. Robbins, New York City

5:15 SOCIAL HOUR

6:30 DINNER

8:00 GUEST SPEAKER; Ashley Montagu, Ph.D., Princeton, New Jersey; Renowned Anthropologist and Author.
Subject: Anthropological Observations of the Human Breast.

TECHNICAL EXHIBITS

Aetna Life and Casualty, Hartford, Connecticut
Ayerst Laboratories, New York, New York
Sanford C. Bernstein and Company, New York, New York
Cardio-Respiratory Services Corporation, Darien, Connecticut
Coca-Cola, U.S.A.
Datamedic Corporation, Manhasset, New York
Arthur W. Eade Agency, New Haven, Connecticut
The Emko Company, St. Louis, Missouri
Group Insurers, Inc., Hamden, Connecticut
Hoechst-Roussel Pharmaceuticals, Inc., Somerville, New Jersey
Homemakers Upjohn Company, West Hartford, Connecticut
Keter, Inc., New York, New York
Eli Lilly and Company, Indianapolis, Indiana
Meade Johnson Laboratories, Evansville, Indiana
Medical Advanced Systems, Inc., Belmont, Massachusetts
Medical Personnel Pool, Hartford, Connecticut
Mutual Benefit Life Insurance Company,
Farmington, Connecticut
Parke Davis and Company, Detroit, Michigan
The Purdue Frederick Company, Norwalk, Connecticut
The Upjohn Company, Needham Heights, Massachusetts
United States Air Force Medical Services

SPECIAL NOTICE

THE CONNECTICUT STATE MEDICAL SOCIETY
acknowledges with thanks
convention program grants received from:

Geigy Pharmaceuticals, Ardsley, New York
Merck Sharp & Dohme Postgraduate Program
A. H. Robins Company, Inc., Richmond, Virginia
Roche Laboratories, Nutley, New Jersey
Smith Kline and French Corporation, Philadelphia, Pennsylvania

Principles of National Health Insurance Formulated by AMA

President Ford has indicated that the national health insurance plan he will submit to the 94th Congress will be similar to former President Nixon's Comprehensive Health Insurance Plan (CHIP) which was based on mandatory coverage of workers by employers through the existing private health insurance system.

Meanwhile, HEW Secretary Caspar Weinberger has been meeting with principal medical and health care providers including the AMA in an effort to arrive at some sort of consensus with respect to a NHI bill.

The AMA has provided a 14-point set of principles that it believes essential in any NHI plan. Approved by the AMA Board of Trustees, these NHI guidelines are:

- Minimum federal involvement in administration of any national health insurance program.
- State jurisdiction with respect to licensure and certification of professional health personnel and regulation of insurance.
- Minimum federal dollars in financing of programs for comprehensive coverage at least possible cost.
- Funding through federal, state, and private funds including (a) employer-employee contributions for private health insurance, and (b) an individual tax credit as applied for full health care protection.
- No added social security tax for financing.
- No administration by social security.
- Cost sharing by participating individuals and families and a subsidy for the indigent scaled according to income.
- Use of private insurance on risk and underwriting basis.
- Comprehensive coverage, basic and catastrophic, for the entire population.
- Pluralism in methods of health care delivery.
- Cost controls as appropriate.
- Quality controls as appropriate.
- Continuity of benefits.
- Coordination of benefits.

FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, Conn. 06511
Telephone 865-0587

Francis G. Sweeney
Assistant Executive Director
Public Affairs

William R. Richards, M.D.
Executive Director
Josephine P. Lindquist
Associate Executive Director

Leonard R. Tomat
Assistant Executive Director
Scientific Activities

Summary of Actions
Council Meetings
Thursday, February 20, 1975

I. Attendance

Present in addition to the Chairman, Dr. D. A. Grendon, and the Vice Chairman, Dr. C. W. Johnson, were: Drs. Root, Jr., VanSyckle, Spitz, Backhus, Brandon, Nolan, Gardner, Fabro, Hess, Cramer, Kamens, Rubinow, Ragland, Jr., James, Freedman, Krinsky, Dambeck, Roch, Beck, McGarry, Canzonetti, Harkins, Magram, Mendillo, Barrett and Klare.

Also present were: Mrs. Lindquist, Mr. Tomat, Mr. Sweeney and Dr. Richards.

Absent were: Drs. Bradley, Granoff, Sadowski, Eslami and Sonnen.

II. Routine Business

Approval of Minutes

As published and distributed, it was VOTED to approve the minutes of the meeting of January 15, 1975.

Life Memberships

It was VOTED to approve applications for Life Membership received from the following eligible Active Members:

William Bria, Diamond Hill, Cos Cob
David H. Clement, 237 East Rock Road, New Haven
James R. Cullen, 581 Hall Hill Road, Somers
Henry D. Fearon, Washington, CT
Paul R. Johnson, 85 Jefferson Street, Hartford
Joseph Mignone, 1450 Chapel Street, New Haven
Sal A. Prins, 67 Old Mill Road, Middletown
Isidore Schnap, 85 Jefferson Street, Hartford
Benjamin Sherman, 156 Palmetto Ave., Unit No. 16, Indialantic, Fla.
Fred F. Tirella, 85 Beleden Gardens, Bristol
Charles F. VonSalzen, 85 Jefferson Street, Hartford

Election of Student Members

It was VOTED to elect to Student Membership four medical students as follows:

Stephen J. Kolesk, 172 Nells Rock Rd., Shelton
University of Connecticut—Class of 1978
Pre-Med: Fordham University.
Parent: Mitchell Marcinauskis

John J. Lynch, 472 Old Mill Road, Fairfield
Creighton University—Class of 1978
Pre-Med: Fairfield University
Parent: Thomas P. Lynch

Jane L. Tyler, 980 Galloping Hill Road, Fairfield
Georgetown University—Class of 1978
Pre-Med: Georgetown University
Parent: Richard F. Tyler

Peter B. Wittstein, 5A Brickyard Rd., Farmington
University of Connecticut—Class of 1978
Pre-Med: Boston University & Fairfield University
Parent: Ansel Wittstein

Date of Next Meeting

The Chairman set Wednesday, March 19, 1975 as the date of the next meeting.

III. Old, New and Special Business

Resignations, Appointments, Etc.

(a) *CSMS Representatives, CHA Advisory Committee on Professional Liability:* It was VOTED to appoint M. David Deren, Bridgeport, and Timothy F. Nolan, Greenwich, to serve as CSMS representatives on the Advisory Committee on Professional Liability and Loss Control of the Connecticut Hospital Association. Drs. Deren and Nolan are members of the CSMS Committee on Professional Liability (chairman and co-chairman respectively).

(b) *CSMS Representative, Connecticut Family Planning Council:* It was VOTED to accept for filing notice that Leroy H. Wardner, Hartford, can no longer serve as a CSMS representative on the subject Council. It was further VOTED to request Gary F. Nobert, Avon, to serve in place of Dr. Wardner and to defer action on the appointment until Dr. Nobert's availability and willingness to serve have been determined.

(c) *CSMS Representative, Affiliated Institutions Committee, Yale Cancer Center:* It was VOTED to accept the resignation of Robert S. Martin, Hartford, as CSMS representative on the subject Committee, and it was further VOTED to appoint

Henry Williams, Hartford, to replace Dr. Martin in that post.

(d) *CSMS Representatives, CHA Agencies:* At the request of the President of the Connecticut Hospital Association, it was VOTED to appoint William E. Lattanzi, New Haven, to serve on a Technical Advisory Committee to an inpatient pediatric care study, to replace James H. Root, Jr., Waterbury.

(e) *Nominations, AMA Council:* Being invited to make nominations for AMA Council elected by the House of Delegates and/or appointed by the President, it was VOTED to submit the name of E. Tremain Bradley, Norwalk, as a Council-endorsed candidate for appointment to the AMA Judicial Council. This appointment is made by the AMA President.

"COUNCIL CAPSULES"—P.L. 93-641, Health Resources and Planning Act of 1974

It was VOTED to accept for filing a package of information ("COUNCIL CAPSULES") relating to P.L. 93-641, with special reference to current activities being engaged in to implement the new law in Connecticut. The Council members were joined by Mrs. Sarah Hirakis, M.P.H., Deputy Director of the Health Planning Division, State Commission on Hospitals and Health Care, who presented a resume of the essential provisions of the Law, the timetable for its implementation and a series of personal opinions as to what ultimate effects the measure will have on the practice of medicine, group settings, PSROs, etc. The informational materials and the presentation of Mrs. Hirakis engendered much discussion and many expressions of concern for the future of private medicine, but no further action was taken on the subject.

Report—Subcommittee on Preliminary Study of Nominations

After making several amendments, the Council VOTED to approve the report of the Subcommittee which presented a slate of officers, committees, etc. to be elected by the House of Delegates on April 30, 1975, and to transmit such slate to the House with Council recommendation for approval.

Followup Report—
CHHC Primary Care Questionnaire

It was VOTED to receive as information copies of two letters addressed to the Chairman, David A. Grendon, from (a) James E. C. Walker, Hartford, chairman of Committee No. 1 of the Task Force on Primary Care of the Commission on Hospitals and Health Care, and (b) Sarah S. Hirakis, Deputy Director, Health Planning Division, CHHC. Both communications were in response to a letter written by Dr. Grendon to James D. Whitten, Chairman of the CHHC, in which the Council Chairman commented that prior consultation with the Society about the questionnaire might have proven advantageous to all concerned and expressed hope that the CHHC Task Force might elect to continue its study of primary care in concert with the CSMS Committee on Statewide Medical Planning and other committees of the Society.

Abolishment of Committee on VD Education and Control

It was VOTED to approve a recommendation of the Committee on VD Education and Control that the Committee be abolished and that the functions of the Committee be taken over by the Committee on Public Health or a subcommittee thereof. It was further VOTED to recommend approval of this action by the House of Delegates on April 30.

Communication—Committee on Maternal Morbidity and Mortality

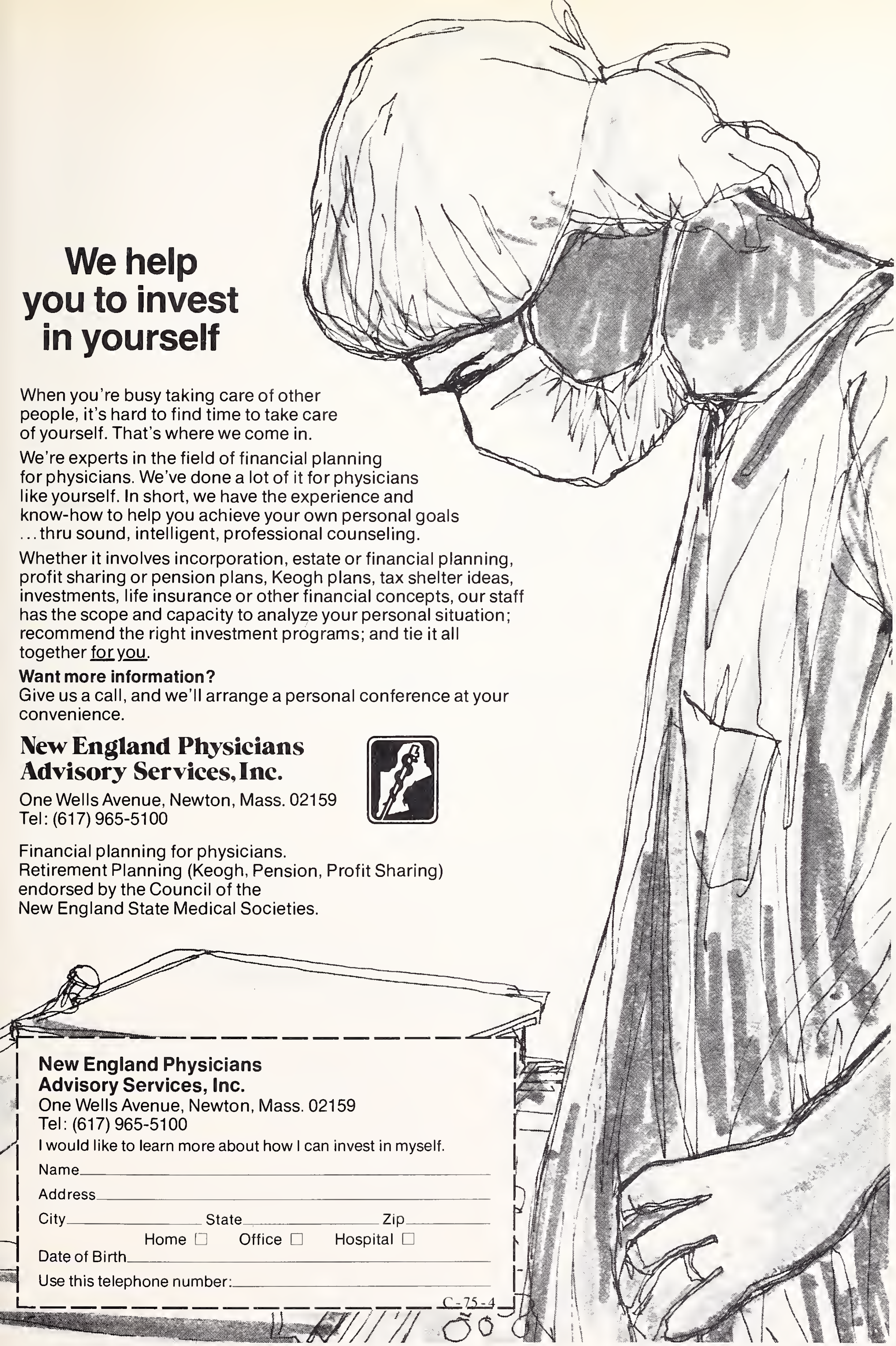
It was VOTED to approve a recommendation of the Committee on Maternal Morbidity and Mortality that the present allowed strength of 24 members be removed, and it was further VOTED to recommend to the House of Delegates that this action be approved by the House on April 30.

Report—Committee on Drug Abuse Education

It was VOTED to approve a recommendation of the Committee that a form, titled "Police-Alcohol Treatment Facility Information Form," be endorsed by the Council for the Society. The form was developed to be used in hospital facilities and was formulated jointly by the Committee on Drug Abuse Education, the Committee on Accident Prevention and EMS, the Connecticut Hospital Association, the State Department of Mental Health and the Connecticut Municipal Police Training Academy.

The Malpractice Insurance Problem

It was VOTED to support a resolution adopted by the Litchfield Association at a recent meeting which endorsed Proposed Bill No. 6424 (1975 General Assembly), AN ACT CONCERNING ATTORNEYS' FEES IN CASES OF MALPRACTICE SUITS AGAINST PHYSICIANS AND SURGEONS. Introduced by Rep. Metro, 64th District, the bill would require the plaintiff to pay the legal fees of the defendant (physician) if the court finds in favor of the defendant. It was also VOTED to accept for filing a report submitted by the Commit-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C-75-4

tee on Professional Liability and to approve Committee recommendations (with minor changes) as follows:

(1) That the Council request Governor Grasso to appoint a commission, or an appropriately constituted body, to study the problem of professional liability coverage for physicians in Connecticut and to make recommendations for legislation designed to alleviate the present critical situation.

(2) That the Council suggest to the Governor that such a study commission or study group might include as members: consumers, the insurance industry, the medical profession, legal profession, hospital administrators and any others that the Governor may deem appropriate.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on Feb. 20, 1975. Detailed minutes of the meeting are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

Welcome, New Members

Litchfield County

Joseph Rich, M.D., Washington Road, Terryville, Conn. 06786

Tolland County

Edna J. M. Arrieta, M.D., Rockville General Hospital, Rockville, Conn. 06066
Robert S. Cook, Jr., M.D., 57 Union Street, Rockville, Conn. 06066
Balasubramaniam Dhandapani, M.D., Tolland Professional Bldg., Route 30, Rockville, Conn. 06066
Clairemon Reyes, M.D., Rockville General Hospital, Rockville, Conn. 06066
Thomas J. Taylor, M.D., Emergency Room, Rockville Hospital, Rockville, Conn. 06066
Marion A. Warpinski, M.D., 37 East Street, Stafford Springs, Conn. 06076

Middlesex County

Vincent J. Catrini, M.D., 770 Saybrook Road, Middletown, Conn. 06457
Kenneth L. Eckhart, M.D., 22 Michele Drive, Portland, Conn. 06480
David B. Kalayjian, M.D., 1251 South Main Street, Middletown, Conn. 06457
Daniel C. Niejadlik, M.D., 17 Michele Drive, Portland, Conn. 06480
Dale Rowett, M.D., Pheasant Hill Road, Old Saybrook, Conn. 06475
Rita C. Sinnamon, M.D., 49 Brainerd Avenue, Middletown, Conn. 06457
Elise W. Snyder, M.D., Cedar Swamp Road, Deep River, Conn. 06417
Eric J. Thomas, M.D., 395 Main Street, Old Saybrook, Conn. 06475
Daniel Hoffman, M.D., 60 Trolley Crossing, Middletown, Conn. 06457
Paul S. Pierson, M.D., 26 Main Street, Essex, Conn. 06426
Edward S. Tucker, M.D., 64A North Main Street, Essex, Conn. 06426
James O. van Bavel, M.D., 121 Highland Avenue, Middletown, Conn. 06457

New London County

Jyotsna R. Chheda, M.D., Lawrence and Memorial Hospitals, New London, Conn. 06320
Harrison M. Dickson, M.D., U.S. Coast Guard Academy Hospital, New London, Conn. 06320
Daniel Gilmartin, M.D., William W. Backus Hospital, Norwich, Conn. 06360
Padam C. Jain, M.D., P.O. Box 508, Norwich, Conn. 06360
Adisayam J. Kantharaj, M.D., 35 Lafayette Street, Norwich, Conn. 06360
Thomas H. Lesnik, M.D., 159 Sachem Street, Norwich, Conn. 06360
Dennis S. Long, M.D., Route 12, Gales Ferry, Conn. 06335
C. Francis Roe, M.D., 365 Montauk Avenue, New London, Conn. 06320
A. Gordon Murphy, M.D., Connecticut College, New London, Conn. 06320
John H. Sutphen, M.D., Lawrence and Memorial Hospitals, New London, Conn. 06320

Fairfield County

Steven P. Mickley, M.D., 239 Glenville Road, Greenwich, Conn. 06830
Yong J. Park, M.D., 50 Ridgefield Avenue, Bridgeport, Conn. 06610
Vijay M. Patil, M.D., Clapboard Ridge Road, Brookfield, Conn. 06804
Noel I. Robin, M.D., Stamford Hospital, Stamford, Conn. 06902
Wittaya Ruangyuttikarn, M.D., 55 Ridgefield Avenue, Bridgeport, Conn. 06610
Richard M. Sallick, M.D., Norwalk Hospital, Norwalk, Conn. 06856
Hossein Samai, M.D., Norwalk Hospital, Norwalk, Conn. 06856
James A. Slater, M.D., 164-C Essex Ridge, New Canaan, Conn. 06840
Itschak Tidhar, M.D., 325 Reef Road, Fairfield, Conn. 06430
Stephen D. Wolanske, M.D., 4 Dearfield Drive, Greenwich, Conn. 06830

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiry of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511, (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine.*

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

OB/GYN: Board certified OB/GYN seeks associate to join busy solo practice in large city in CT. Must be Board certified or eligible. Ability to speak Spanish essential. Salary then partnership. Send resume to B.C. c/o CSMS.

Pediatrician: Need for pediatrician in Southbury area. Contact CSMS.

Thoracic and General Surgery: Board certified associate needed for group practice. Write NT. CT. CSMS.

Radiologist: To join group in central Connecticut. Private office practice combined with teaching opportunity at university affiliated hospital. Salary negotiable. Send resume to Radiology, c/o CSMS Physician Placement Service.

Pediatricians: Several opportunities for full and part time positions with the State Office of Mental Retardation. Internist and Family Practitioners will be considered. Full time positions require board certification or eligibility. Salary mid twenties plus housing. Write Sherwin Mellins, M.D., Director of Medical Services, Office of Mental Retardation, State Department of Health, 79 Elm Street, Hartford, Connecticut 06115.

Family Practice: Group in Farmington seeking primary care physician. Possible partnership or coverage for weekends, vacations and emergencies. Send resume to E.H.D., c/o CSMS.

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

(If no name is listed, contact the Physicians Placement Service)

Anesthesiology: Available July 1975. Board eligible. FLEX. Group or Associate Practice. Completing residency at Beth Israel Medical Center in New York. Bienvenido S. Lee, M.D., 100 East 92nd Street, No. 2A, Brooklyn, N.Y. 11212.

E.N.T.: Board certified, 1973. Presently in practice in greater New York City area. Solo practice desired. 42 years old. FLEX. Trained at Long Island Hospital and St. Luke's in New York.

Cardiology: Available July 1975. Group or Associate Practice. Board certified. Prefers clinical cardiology with limited general medicine. Michael S. Bensman, M.D., 4360 Baychester Avenue, Bronx, N.Y. 10466.

Internal Medicine—Cardiology: Board eligible. Available July 1975. Mass. license and F.L.E.X. Group or Associate Practice desired. Age 35. Married. Formerly on medical faculty in Yugoslavia. Presently fellow at Boston City Hospital. Zeljko Freiberger, M.D., 47 Fenno Rd., Newton Centre, MA. 02159.

Internal Medicine: Board eligible. Conn. license. Group, Associate, Institutional or Industrial Practice. Presently at Bridgeport Hospital. Available July 1975. M. Rama Chandran, M.D., 1700 Broadbridge Avenue, Stratford, CT. 06497.

Internal Medicine—Cardiology: Board eligible. New York license. Desires medium or small community in Group or Associate Practice. Primary care. Presently at Montefiore in N.Y. Elliot M. Rudnitzky, M.D., 3450 21 Wayne Ave., N.Y., N.Y., 10467.

Internal Medicine: Desires position as house physician or in emergency room. F.L.E.X. to be taken in June 1975. Available July 1975. 32 yrs. old. Presently in hepatology residency at N.J. College of Medicine. K.F. M.D. c/o CSMS.

Internal Medicine: Certified. ABIM. Presently holds full time academic appt. in oncology. Desires part time in hematology and oncology. Connecticut license. Mark A. Tuckfelt, M.D., 36 Florida Hill Road, Ridgefield, CT. 06877.

General Medicine and Infectious Diseases: Available July 1975. Board eligible. Passed F.L.E.X. 32 years old. Presently fellow at University of South Carolina. Mohammad A. Khan, M.D., 1175 Mathis Ferry Rd., Apt. E-2, Mount Pleasant, S.C. 29464.

Internal Medicine: Cardiology. Board Certified. Presently in Air Force. Group or associate practice. Available mid 1975. Richard F. Gordon, M.D., 109-A Birch Circle, Elgin Air Force Base, Florida 32542.

Internal Medicine: Board eligible, Connecticut license. Gastroenterology. Desires group of general internists with subspecialties. Available July 1975.

Internal Medicine: Board eligible. Solo or industrial medicine. Available July 1975. New York and Connecticut License. 31 years old. Peter Sereny, M.D., 353 East 17th Street, 25C., New York, New York 10003.

Internal Medicine—Gastroenterology: Associate or Group Practice. Board eligible. Presently GI Fellow at Rhode Island Hospital in Providence. 33 years old. Married. Available July 1975. A. S. Sripathi Karanth, M.D., 331 Prospect Street, Apt. 20, Pawtucket, R.I. 02860.

Internal Medicine (Cardiology): Group or Associate type practice. Board eligible. Trained at Mt. Sinai Hospital in Cleveland and Sinai of Detroit. Available July 1975. 31 years old. Umakant S. Doctor, M.D., 14925 Greenfield Road, Detroit, MI. 48227.

Internal Medicine (Infectious Disease): Board certified in infectious disease. Seeking position as full time chairman of a dept. of internal medicine with teaching and administrative responsibilities. Available immediately. Johns Hopkins and University of Chicago Hospital. Richard Finley, M.D., 405 Bell Downs Drive, Lafayette, LA. 70501.

Internal Medicine (Endocrinology and Hypertension): Available April 1975. Conn. license. Board eligible. Internship and first year residency at Hartford Hospital. Group practice. 37 years old. Married. Wishes to return to Conn. in group practice. Norman J. Kramer, M.D., 7721-A Ivydale Drive, Indianapolis, Ind. 46250.

Internal Medicine: Board eligible. Available July 1, 1975. Solo, group or associate practice in medium sized community. 36 years old. Married. Completing residency. Cheng-Chu Wu, M.D., Bergen Pines County Hospital, Paramus, N.J., 07652.

Internal Medicine: Presently in practice. Wishes to relocate from greater New York City area. Connecticut license. 36 years old. Cornell and New York Medical School. E.M.G., M.D., c/o CSMS.

Internal Medicine (Nuclear Medicine): Board certified. Full time nuclear medicine, within commuting distance to New York City. Available July 1975. Herbert A. Klein, M.D., 65-15 Alderton Street No. 3D, Rego Park, N.Y. 11374.

Internal Medicine (Gastroenterology): Board eligible. Available July 1975. Experience in upper G.I. endoscopy, colonoscopy and peritoneoscopy. Presently at Sloan-Kettering Cancer Center, New York. Man-Siak Mak, M.D., 1770 Grand Concourse, No. 2K, Bronx, N.Y. 10457.

Family Practice or Emergency Medicine: Presently in practice in greater New Haven area. Wishes to relocate. Conn. license. A.B.F.P. Yale University School of Medicine, 1970. Yale graduate program. Charter member of Am. College of Emergency Physicians. Write L.R.B., M.D., c/o CSMS.

Family Practice: Board eligible. Immigrant. Available Nov. 1975. Group or Associate. Guaranteed salary or hospital based appointment desired. N.Y. license. FLEX. K. Thekkethala, M.D., 660 E. 98th St., 4-G, Brooklyn, N.Y. 11236.

Neurology: Board eligible. Available July 1975. 32 years old. Experienced in EEG, EMG. Solo, Group or Associate Practice. Currently serving in armed forces. Trained at Louisiana State University Medical Center. JES MD, c/o CSMS.

Neurology: Board eligible. Available July 1975. Group or Associate Practice. Harvard, University of Chicago Medical School, University of California in San Francisco. 32 years old. Married. 2 years experience in USPHS. Richard M. Lowenthal, M.D., 1459 Fifth Avenue, San Francisco, CA. 94122.

Ophthalmology: Board eligible. 35 years old. Available July 1975. Head fellow at Guthrie Clinic-Robert Packer Hospital, Sayre, Penna. Ferdinand R. Schwarz, M.D., 1192 Temple Drive, Yardley, PA. 19067.

Orthopaedic Surgery: Board eligible as of July 1975. Available summer of 1975. Johns Hopkins, George Washington University, St. Vincent's and Downstate Medical Centers, N.Y.C. Age: 32. Completed two years of active service. Married. DeWitt C. Brown, III, M.D., 2736 Independence Avenue, Riverdale, N.Y. 10463.

Pathology: Board certified C.P. and H.P. Group or Associate Practice. Large or medium sized community. Available July 1975. Two years with U.S. Naval Hospital. Antonio Tamara, M.D., 1738 Aberdeen Road, Baltimore, MD. 21234.

Pediatrics: Available July 1975. Massachusetts license. Princeton, Tufts Medical and New England Medical Center. Medium or small community desired with group or associate practice. 31 years old. Married, 2 years in Army Medical Corps. Charles J. Okstein, M.D., 30 Beaver Brook Road, Sharon, Mass. 02067.

Physician's Asst.: Available in June 1975. Currently enrolled in program. 30 years old. Four years in U.S.N. Hospital. Certified respiratory technician. Desires position with primary care or specialty group. James E. Thompson, 1011 West Avenue, Elyria, OH. 44035.

General Surgery: FLEX. Board eligible. Presently clinical assistant in surgery at Bellevue Hospital, New York City. Available immediately. 37 years old. Joseph E. Veizagal, M.D., 1675 York Avenue, Apt. 3M, N.Y., N.Y. 10028.

General Surgery: (with General Practice and/or E.R.). Board eligible. FLEX. Pennsylvania license, 31 years old. B.N. Doshi, M.D., 4180 Warrensville Center Road, Cleveland, O. 44122.

General Surgery: Available in July 1975. Presently at Mt. Sinai in Hartford. University of Peru. Buffalo General Hospital, New York. Board eligible. Jorge A. Melendez, M.D., 891 West Blvd., No. 103, Hartford, CT. 06105.

Surgery—General: General and Vascular. Trained in colonoscopy. 28 years old. Available July 1975. Board eligible. Allen B. Davis, M.D., Oak Hill Apt. E-211, Penn Valley, Pennsylvania 19072.

Surgery—Orthopaedic: General orthopaedics with reconstructive surgery. Available mid 1975. Harvard trained.

Surgery—Orthopaedic: Group or associate practice. Available July 1975. Board eligible. New York license. Tufts, Albany Medical College. Upstate Medical Center, Syracuse. Robert M. Sheridan, M.D., 18 Pickwick Road, Dewitt, New York 13214.

Urology: Board eligible. Available July 1975. FLEX. Residency at Tufts and Beth Israel Medical Center, Mt. Sinai School of Medicine, New York City. 32 years old. Lawrence H. Spiro, M.D., 353 East 17th Street, Apt. No. 9B, N.Y., N.Y. 10003.

Urology: Board eligible. Completed residency at Upstate Medical Center, Syracuse, New York. Presently in practice. Prefers larger or medium size community with group or associate practice. Gerald Frankel, M.D., 6204 Newberry Rd., Indianapolis, IN. 46256.

Urology: Board eligible. Passed part I. Available July 1975. Presently in practice. Desires group practice. 35 years old. Samuel Aronson, M.D., 496 Wintergreen Way, Rochester, N.Y.

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Connecticut Medicine

The Journal of the Connecticut State Medical Society

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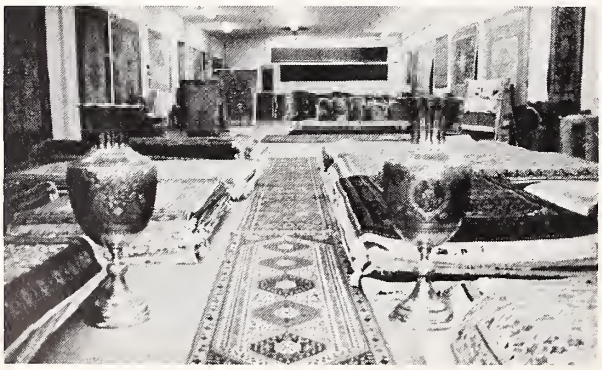

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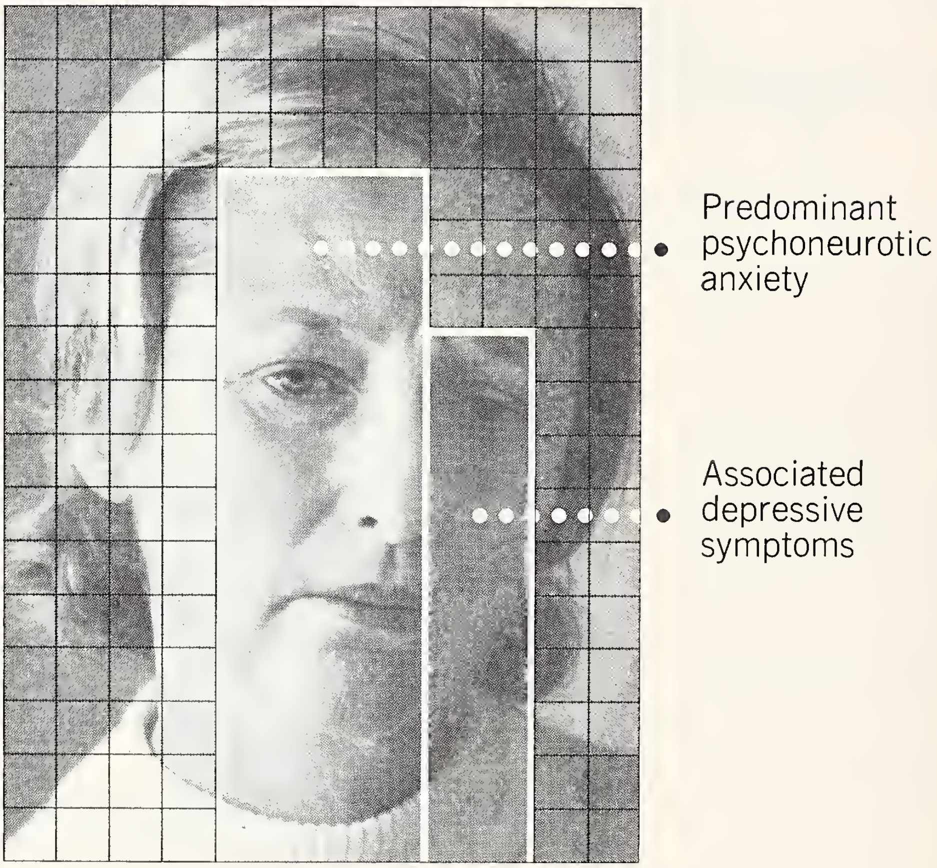
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Lung Cancer

Harold Stern, M.D. and Allan L. Toole, M.D.

The first successful operation for lung cancer was a pneumonectomy which was done by Everts Graham in 1932 in St. Louis, Missouri. This was for a squamous cell carcinoma in a physician from New York State. The obstetrician developed an empyema following his pneumonectomy but survived longer than the surgeon who died some 23 years later of cancer of the lung that presented with lymphangitic spread. This vividly demonstrates the variable nature of presentation and curability of these tumors.

Little really has changed since 1932. Surgical resection is still the treatment of choice in early cases and in cases of appropriate cell type. The only consistent significant survival has been with surgery although there are occasional cases of documented cure by X-ray therapy alone. Spontaneous regression of tumors has been reported, also. Individual assessment of the patient is essential. It is unwise to relegate patients categorically as operable or inoperable on the basis of statistics alone. Studies which make sweeping generalizations may be valid only for the institution involved. Radiation therapy and surgical results certainly vary from one facility to another. It is the clinical impression of one group at Yale-New Haven Hospital that pre-operative radiation has a definite place in selected cases. This is at variance with one report.[1] Recently Bates et al reported an exciting series of patients with oat cell carcinoma treated by pre-operative radiation and surgery with a 24% four year survival rate.[2] Presently our group continues to select certain patients for pre-operative radiation therapy and definitive surgery. The complication rate is no greater in this group than in the non-irradiated group. This, too, is at variance with published reports.[1]

Pulmonary resection is still the treatment of choice for lung cancer. Limited resection, such as lobectomy, is preferable to pneumonectomy to preserve lung function, resulting in decreasing morbidity, both immediate and long term. With the aid of post-operative respiratory assistance, formerly inoperable patients are now able to withstand resection.

Oat cell carcinoma is generally so lethal that surgery is not undertaken. However, sometimes carcinoid tumors masquerade as oat cell carcinoma.[3] Therefore, patients whose cytology or biopsy is "oat cell cancer" should not be considered inoperable if clinically carcinoid tumor is suspected. At the other end of the spectrum is the scar cancer. Excellent results are obtained in patients with this tumor, first described by Spencer.[4] These tumors, since they originate in scars which may be noted on old films, may represent difficult diagnostic problems. In addition, adjacent honeycombing may further suggest inflammatory disease. Exploratory thoracotomy is usually necessary for diagnosis.

Contraindications to thoracotomy have not changed in recent years. They include recurrent nerve involvement, pleural effusion and, of course, distant metastases. "Palliative" surgery is rarely indicated.

Relative contraindications to surgery vary with the aggressiveness of the surgeon and of the institution. One of these includes local invasion of the chest wall. Our group, and others,[5] have obtained long-term survivors with local chest wall resection in continuity with lobectomy. Age is no contraindication to surgery. Bronchoscopy with brushing is frequently used. A negative bronchoscopy and brushing does not rule out cancer. One should rely only on positive bronchial brushings for definitive diagnosis. The usual workup includes bronchoscopy and scalene node biopsy, both done under topical or local anesthesia, and with no morbidity. Mediastinal nodes are obtained when indicated by way of an anterior mediastinotomy. The goal is to decrease the number of exploratory thoracotomies alone. Ideally this number should approach zero, but the low morbidity of exploratory thoracotomy alone does not preclude its use.

Needle biopsy, which is gaining popularity, should be reserved for those patients who have inoperable cancer. It is inadvisable to place a needle through the chest wall and normal lung parenchyma into a peripheral lesion for a tissue diagnosis. In patients with no evidence of metastasis the needle biopsy should be deferred to a thoracotomy. On the other hand, needle biopsy of the pleura can be very

---

DR. HAROLD STERN, Associate Clinical Professor, Cardiothoracic Surgery and DR. ALLAN L. TOOLE, Assistant Clinical Professor, Cardiothoracic Surgery, both of Yale University School of Medicine.

This paper and the following three papers are based on a talk given at a post-graduate symposium on "Current Concepts in Cancer Management," November, 1973. The symposium was sponsored by the Office of Regional Activities and Continuing Education and the Section of Medical Oncology, Yale University School of Medicine.

The symposium coordinator and editor for these articles is Dr. Roland T. Skeel, Associate Professor of Medicine and Pharmacology, Yale University School of Medicine. The support of the Connecticut Division of the American Cancer Society is gratefully acknowledged.

helpful, and also biopsy of tumors invading the chest wall. All patients are subjected to radio-isotope scanning of liver and brain.

The result of surgery in patients who have peripheral (metabolic, hormonal) manifestations of lung cancer has been very disappointing. Many of the metabolic effects are associated with oat cell carcinoma. Cures are rare in those who present with pulmonary osetoarthropathy. Likewise, inappropriate ADA secretion is associated with incurable cancer. On the other hand, the carcinoid syndrome associated with carcinoid tumor may have an excellent prognosis.

One of the best modalities for palliation of malignant pleural effusion is a simple chest tube insertion and instillation of nitrogen mustard.

Criteria for surgery of metastatic tumors to the lung have remained static and should include the following: First, the primary cancer should be under control. Secondly, the primary cancer should have been treated adequately long before the secondary tumor is obvious. The patient whose primary cancer is noted simultaneously with the metastatic tumor has a poor prognosis. Thirdly, certain metastases should not be treated surgically, particularly breast carcinoma. Fourth, multiple metastases are rarely helped except if confined to one lobe.

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The Importance of Pathology for Prognosis and Management in Lung Cancer

Raymond Yesner, M.D.

The World Health Organization's classification of carcinomas of the lung, adopted in Geneva in 1965, is too complex for consideration here. In time, it may yield additional important information, but within the scope of current knowledge many details are not important in the prognosis and management of lung cancer. Nor are we concerned here with sarcomas or carcinoids. The major histologic classes of lung cancer under consideration are squamous cell carcinoma, small cell carcinoma, adenocarcinoma, and large cell carcinoma.

Squamous Cell Carcinomas

Squamous cell carcinomas are defined as those carcinomas having definable keratin and/or intercellular bridges with light microscopy. These characteristics, together with large nuclei, prominent nucleoli, abundant cytoplasm, usually positive for glycogen with well-defined cell borders and with no mucin within the cells, marked host response (tumor antibodies have been demonstrated in the blood serum) in the forms of desmoplasia, lymphocytes, plasma cells and eosinophiles, and discrete, cohesive tumor nests, frequently with palisaded peripheral cells, enables the trained pathologist to make the diagnosis, based on typical biopsy material, with approximately 98% degree of reliability.[1] If he does not use these criteria, but relies instead on a squamatoid appearance, without demonstrable keratin or bridges, the degree of reliability drops to less than 50%. It is for that reason that such tumors are classed with the large cell undifferentiated carcinomas, even though tonofibrils and desmosomes may be demonstrable by electron microscopy.

The differentiated squamous carcinomas (WHO types 1a and 1b) comprised 28% of all positive lung cancer biopsy material in a study of 2897 biopsies by the VA Lung Group.[1] Of the 1120 bronchial biopsies, 43% were differentiated squamous carcinomas. Conversely, 59% of such carcinomas were diagnosed by bronchial biopsy. Thus, it tends to be a centrally placed tumor, available to the bronchoscope. Its cells are recognized in the sputum more often than those of other cell types because of its tendency to be centrally placed, to exfoliate tumor cells into the bronchial secretions, and because it is commoner in surgical material than other cell types, and because its cells are usually readily recognized.

Squamous carcinomas are also prone to massive necrosis, and because they originate in large bronchi, the necrotic carcinoma sloughs and the tumor cavitates more extensively than other kinds. Associated with cavitation is exsanguination, which occurred

---

DR. RAYMOND YESNER, Professor of Pathology, Yale Medical School; Chief Pathologist, Veterans Administration Hospital, West Haven, Conn.

twenty-three times more frequently than in the small cell types in the VA Lung Group studies.[2]

The desmoplastic reaction induced by squamous carcinomas causes them to adhere to adjacent structures, particularly the chest wall and mediastinal tissues, which are directly invaded. This important property sometimes makes the tumors difficult to remove surgically, which is unfortunate, since a high percentage of them never metastasize. In 200 cases, followed to autopsy, 50% did not leave the thorax. Patients with this tumor, its aggressive local behavior notwithstanding, tend to live longer than patients with other lung cancers. More patients survive for 5 year and 10 year periods of time. The possibility exists that irradiation can eradicate local disease, and this has rarely been accomplished. Survival time has also been significantly increased by the use of nitrogen mustard, as compared with placebo.[3]

Elevated serum calcium occurs more frequently with squamous carcinoma than with other cell types, and a parathyroid hormone has been detected in the tumors of some patients. If the calcium does not return to normal following resection, or if this tumor is unresectable, irradiation may cause it to do so.

Small Cell Carcinoma

Small cell carcinomas of the lung are a little harder to define than squamous carcinomas, from which they differ in many ways. They are frequently referred to as "oat cell carcinomas," because of the small, oval appearance of the cells. They are also described as lymphocyte-like, and indeed some resemble lymphocytes. Others palisade around blood vessels, and assume a compact spindle shape elsewhere. All of these exhibit certain common features which include round or oval nuclei of variable density. In the best preserved specimens, the chromatin is fairly uniformly dispersed through the nucleoplasm—this is particularly true of spindle and palisaded cells—and nucleoli are not prominent on light microscopy. The oat-cell and lymphocyte-like cells have pyknotic nuclei. All these cells exhibit scant cytoplasm and a lack of host response. They are easily traumatized, frequently appearing on bronchial biopsy as dense, amorphous basophilic masses—the "crush effect," which is practically diagnostic. In the cytoplasm of small cells may be found on electron microscopy secretory granules, similar to those found in carcinoid cells, and for this reason together with the similarity of light microscopic appearance and the fact that a small percentage of small cell tumors produce anough ACTH to cause symptoms, they are considered by many investigators to be the malignant counterpart of the carcinoid.[2] Small cell tumor cells sometimes grow in ribbon-like patterns along thin-walled blood vessels, and may actually form small acini occasionally. To add to the confusion, transitions may be shown between small cells and differentiated squamous cells and adenocarcinomas, as well as to undifferentiated polygonal cells with larger nuclei, more abundant cytoplasm, and giant cells with multiple pyknotic nuclei. Because of this spectrum, the W.H.O. has classified the small cell carcinomas into spindle-cell, polygonal, and lymphocyte-like sub-groups. We have found little reason to differentiate among the cell types other than the polygonal, and classify them as small cell carcinomas (VALG: 2a), with 90% reliability as judged by unanimity of diagnosis by experienced pathologists. The polygonal small cell carcinoma (VALG: 2b) is less reliable, but all forms are currently considered as small cell carcinomas for purposes of management. Small cell carcinomas of the lung are thus defined as tumors having round or oval nuclei, without prominent nucleoli or host response, and generally having scant cytoplasm, so that many more nuclei appear in a given microscopic field. The cytoplasm is negative for mucin, glycogen, or keratin, but may be argentaffin positive.

They comprise 19% of the VALG biopsy material, and 43% of them were obtained by bronchial biopsy. They are therefor prone to be central tumors, like the squamous carcinomas, but unlike them do not undergo massive cavitation or exsanguination. They are at the opposite pole from squamous carcinomas in terms of malignant potential. Autopsy studies of 200 patients with treated small cell carcinoma of the lung, showed that only 6% remained within the thorax. They have a shorter survival time than any other cell type (VALG: mean survival time of 6¾ weeks). There were no 5 year survivors in the VALG, none in 135 patients in the Surgical Adjuvant Study Group, who survived 5 years,[2] and none in the 11 patients in Smith's group of 964 who were operated on and survived more than 10 years.[4] Among more peripheral small-cell carcinomas (solitary pulmonary nodules), 2% of Steele's cases survived 5 years,[5] and 2.6% of Jackman's.[6]

Associated with their high degree of malignancy, the small cell carcinomas are more responsive to irradiation and chemotherapy. In several hundred autopsies reviewed in the VALG, there were only 7 cases without residual tumor, 4 of which were small cell carcinoma, of which 3 had been treated by irradiation. This was also true of Miller's series of 160 patients with small cell carcinoma diagnosed by bronchial biopsy. This probably cannot be much improved since other studies have shown that therapy directed only locally does not change the gross survival rate.[7] The 4 patients who survived 5 years (2.5%) received radiotherapy without surgery. Selawry reported that 50% of patients with small cell carcinomas responded to cyclophosphamide by reduction of tumor mass.[8] The VALG has long used cyclophosphamide in lieu of placebo in planned clinical trials.

Although secretory granules and "big ACTH" have been found in other lung cancers,[9] [10] small cell carcinomas may develop sufficient ACTH and other polypeptides to produce hormonal effects, particularly Cushing's syndrome, anti-diuretic hormone-like activity, atypical carcinoid syndrome, and carcinomatous neuromyopathy.[11] The Cushing's syndrome may develop sufficient hypokalemic alkalosis to threaten the life of the patient, if left untreated.[12]

Adenocarcinomas

The adenocarcinoma is a gland-forming tumor. It may form acini (VALG: 3a), or it may form papillary structures (VALG: 3b). Most of those which form acini and about 80% of the papillary adenocarcinomas are mucin-producing. In addition, more solid tumors are found, with no or poor gland formation, which produce stainable mucin within cells. These are classed by W.H.O. as IV-1, a variety of large cell undifferentiated carcinoma. We prefer to call them poorly differentiated adenocarcinomas (VALG: 3c), since most of them can be shown to form acini in some areas. All adenocarcinomas comprised 16% of the VALG surgical material.

In general, the adenocarcinomas tend to occur peripheral to the nominate bronchi. In the VALG study, only 5% of bronchial biopsies yielded adenocarcinoma, and only 12% of the adenocarcinomas appeared in bronchial biopsy material. On the other hand, if peripheral carcinomas are examined, such as Steele's solitary nodule study, adenocarcinomas occur more frequently than any other variety. Adenocarcinomas are also the commonest lung cancer in non-smokers. Such peripheral tumors are often associated with scars, such as old tuberculosis, or simply fibrotic lungs, as in honey-combing or scleroderma, and are apt to be papillary in form, and to grow along pre-existing septa.[13] Since this is also characteristic of the so-called bronchiolo-alveolar carcinoma, which also tends to grow around a fibrotic focus, and since both forms show transitions to acinus-forming carcinomas, no attempt is made to separate them, and both are called papillary adenocarcinomas. There may be two varieties of bronchiolo-alveolar carcinomas, or mixtures of the two, one derived from the bronchial epithelium and mucus-producing, and the other derived from the pneumonocyte.[14] These peripheral papillary carcinomas have a better survival rate than the more proximal adenocarcinomas. In Jackman's series of 193 solitary nodules measuring up to 4 cm. in diameter, of which 60% were adenocarcinomas, 5 year survival was 45%. In Steele's series of nodules up to 6 cm. in diameter, the 5 year rate was 39%.

Hypertrophic osteoarthropathy was observed by Semple to occur more frequently with peripheral than central tumors.[15] All of those we have examined have been adenocarcinomas, except for one squamous carcinoma. No association with small cell carcinomas has been reported.

Large Cell Carcinomas

These undifferentiated large cells are a mixed bag, a waste-basket group. W.H.O. has divided them into 4 subgroups: IV-1, solid with mucin production; IV-2, solid without mucin production; IV-3, giant cell; IV-4, clear cell. If there is clear cut intracellular mucin production, as in IV-1, and often in IV-3, we classify them as adenocarcinomas. On the other hand, we put squamatoid tumors without keratin or intracellular bridges into this group (IV-2 or IV-4). The large cell undifferentiated carcinoma group constitutes 16% of the VALG study.

Combined Carcinomas

These are lung cancers which exhibit 2 or more definite cell types, and comprise only 2% of lung cancers. Metastases may imitate the parent tumor, or show only the more malignant component.

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Chemotherapy of Lung Cancer

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The increased use of combination chemotherapy, the development of new drugs and the recognition of the importance of the ability to develop and maintain the immune response are noteworthy developments in the nonsurgical, nonradiotherapeutic management of lung cancer. The chemotherapy of lung cancer using single drugs is of marginal effectiveness. The overall response rates are low and responses are partial and brief. In Table 1 are listed some response rates from Selawry using single drugs that are rather optimistic. It should be emphasized that these are tabulations of collected series in the literature, many of which are not completely comparable in that different criteria are used for response. It should also be mentioned that many patients who fail to respond do not appear in the literature. Two major points are evident: (1) That different drugs have different response rates depending on the histologic type and (2) small cell undifferentiated carcinoma is associated with the highest response rate to chemotherapy. The newer agents mentioned in this table include CCNU, a nitrosourea compound, and hexamethamelamine. These are all investigational agents. The others are now available commercially. It is of interest that another relatively new drug, bleomycin, is active against a variety of other epidermoid tumors, but is not very active in epidermoid carcinoma of the lung, dashing many fond hopes originally concerning this drug. Another interesting aspect of the chemotherapy of lung cancer is that adenocarcinoma of the lung does not respond well to 5-fluorouracil, a drug which is quite useful against a variety of other adenocarcinomas, particularly those of the breast, gastrointestinal tract, and ovary.

Combination chemotherapy is just beginning to be evaluated. The basic concept is to combine drugs which have some effectiveness as single agents in such a way as to be tolerable to the host. This generally means drugs with toxicities which are different. Additive depression of the bone marrow has been the greatest problem in this type of chemotherapy; this usually necessitates a reduction of the full doses which are normally tolerated alone.

Chemotherapy has been used as an adjuvant to more successful means of treating lung cancer. A recent investigation in Canada by Bergsagel et al. evaluated the use of intermittent Cytoxan against a variety of localized but inoperable carcinomas of the lung. In this experience Cytoxan given intravenously either for 4 or 8 doses at 3 week intervals in a dose of 1 g/m^2 with radiotherapy was associated with an increased survival as compared to patients who received radiotherapy alone. In the

TABLE 1

. COLLECTED OBJECTIVE RESPONSE RATES OF DIFFERENT TYPES OF LUNG CANCER TO VARIOUS AGENTS (FROM SELAWRY, 1973)

Epidermoid	%	*Adenocarcinoma*	%	*Small cell Undifferentiated ("oat cell")*	%	*Large cell Undifferentiated*	%
Chloroethyl cyclohexyl nitrosourea (CCNU)	41	MTX	32	Pro	67	Pro	35
Nit. mustard (HN2)	33	HN2	29	Cy	50	HN2	27
Methotrexate (MTX)	25	Mitomycin C	27	MTX	50	Cy	23
Adriamycin (Ad)	24	CCNU	24	HN2	39	Hex	17
Procarbazine (Pro)	20	Hexamethylmelamine (Hexa)	20	Hexa	36	CCNU	15
Cytoxan (Cy)	19			Ad	29	MTX	12

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overall group of all lung cancers the total median survival improvement was about 100 days or 3 months. This is a rather modest achievement; nevertheless, it does indicate that Cytoxan given in this way with radiation therapy appears to be an active agent and should be a major component of combinations to be used against this disease.

In this report, oat cell carcinoma showed the best response to Cytoxan as compared to the other histologic types. It is noteworthy that Cytoxan had its greatest effect in controlling manifestations of distant metastases which were not apparent at the time of the original radiation therapy.

In the experience from a large V.A. Hospital in Washington (Hansen et al.) there was a modest increase in overall median survival using a combination of methotrexate, Cytoxan, actinomycin-D, vincristine and radiation therapy as compared to earlier experience with single drugs.

The best results reported in the literature are those of Eagan et al. in the treatment of oat cell carcinoma of the lung. They were treated with local irradiation therapy and intensive combination chemotherapy with Cytoxan, methotrexate and vincristine. At about 9 months maintenance treatment was discontinued in this group of patients and they began to die. Median survival was 12 months compared to a retrospective control group having a 2 month median survival with radiation therapy alone and the V.A. lung study group using Cytoxan in which a median survival of 7 months was achieved (Maurer, L.H., personal communication). The impression from this small but very impressive experience is that this is an improved way of treating oat cell cancer. It should be kept in mind that nearly half of these patients have demonstrable bone marrow metastases at the time of diagnosis. At present this type of treatment is being evaluated in a comparative way by a cooperative inter-institutional group (Acute Leukemia Group B) and a similar study has been begun at Yale.

The use of chemotherapy as an adjuvant to attempted "curative" surgery has not yet been shown to be effective. In the V.A. experience nitrogen mustard at the time of surgery did not influence survival. Cytoxan did have a very modest effect in the oat cell group and did influence survival favorably. A Swiss study has actually reported an adverse effect of Cytoxan as a surgical adjuvant when given on a weekly schedule. A current V.A. study is exploring the use of long term intermittent Cytoxan or Cytoxan-Methotrexate at 5 week intervals. Other drugs currently under consideration for use as surgical adjuvants include CCNU and hydroxyurea.

It is of interest that the ability to mount an immune response seems to be important in predicting which patients will respond to chemotherapy. This has been known to influence the prognosis of surgical therapy in a variety of cancers. A convenient way of evaluating the immune response is to use the tuberculin test if the patient happens to have encountered tuberculosis in the past, or mumps or candida. A more certain way is to use the chemical dinitrochlorobenzene (DNCB) as an immunizing agent. The patients with metastatic bronchogenic carcinoma responded more frequently to CCNU if they had intact DNCB responses than those who did not.

A rather extensive French experience of Israels et al. has shown that patients with metastatic epidermoid or oat cell carcinoma responded more frequently and lived longer if they had a positive tuberculin test than if they did not. Patients who were treated with *C. parvum* as immunotherapy as well as chemotherapy had a longer median survival than those who received the same chemotherapy alone.

Another new direction in the therapy of bronchogenic carcinoma is the use of anticoagulation. In animal tumors heparinization has been associated with decreased metastases; a trial of heparinization followed by Coumadin therapy with or without Cytoxan is being evaluated in metastatic bronchogenic carcinoma by the Eastern Cooperative Oncology Group (ECOG).

It is clear that no single modality of treatment will suffice in control of lung cancer. It is likely that the use of radiotherapy, surgery, multiple drugs and possibly immunotherapy will all be needed to improve the outlook in these diseases. A better stratification of patients with respect to histology, anatomic and functional state and immunologic status is required for the intelligent planning of treatment studies and their interpretations. It is obvious that better cooperation between the various therapeutic disciplines is needed.

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The Role of Radiation Therapy in Bronchogenic Carcinoma

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The incidence of cancer of the lung has risen sharply over the past 30 years; as much as six-fold for the age group 65-74, and the chance of cure remains low, approximately 5-10%. The nature of the therapeutic problem is three-fold involving the primary tumor, regional lymph node involvement and distant metastasis. Attempts at early diagnosis have not yet improved the prognisis[1] since many tumors have spread by the time they become detectable by routine chest film. Patients with distant metastasis are not candidates for a curative attempt at the present time. In patients with localized disease, surgery and radiation therapy offer the only hope of cure.

Patients with well differentiated squamous cell carcinoma, clinically operable, should undergo resection. It is within this group that the small number of survivors is found. Such patients, if inoperable for other reasons (medically), should be treated with radiation therapy in an attempt to cure. In a controlled trial of clinically operable cases with squamous cell carcinoma, patients treated with surgery demonstrated better survival (30% vs. 6% at four years) than those undergoing radical radiation.[2] Patients with less differentiated squamous cell tumors and oat cell carcinomas have a high incidence of distant metastasis at the time of diagnosis even when the disease appears to be operable. A comparative trial by the Medical Research Council in England[3] would seem to indicate that radiation is preferable. To be successful any new approach must combine some form of systemic therapy for distant metastasis with an approach to the local tumor by radiation or surgery.

The value of preoperative radiation has not been established. In many large series of all histologic types, there would seem to be little benefit. This is not surprising when one considers that patients with distant metastasis, all of whom will die, patients with localized disease who may be cured by surgery alone, and patients with regional spread to such a degree that control by radiation is unlikely, will derive no benefit from this treatment. Since this represents the majority of patients with lung cancer, it may make it difficult to detect the benefit in the small group which has limited spread of disease into the areas covered by the radiation therapy. In a series of 29 operable oat cell carcinomas given low dose, preoperative radiation then undergoing surgery, the four year survival was 24%.[4] This is a small series and certainly the survival rates are far better than one would expect. Probably careful patient selection is necessary to show benefit of preoperative radiation.

A thorough search for metastatic disease should always be made before embarking on a radical course of treatment. Since almost all local lesions respond to radiation with a significant reduction in size, one can expect excellent palliation of symptomatic metastasis. Hemoptysis and cough frequently improve in the treatment of the primary lesion. Relief of pain resulting from involvement of the pleura, the lungs and bone is often dramatic. Infection and atelectasis arising from bronchial obstruction can be relieved with the promotion of better drainage. Dyspnea due to major airway obstruction responds well; but when due to extensive lung involvement, for example with lymphangitic spread, it is much more difficult to relieve. Dysphagia due to esophageal compression by tumor responds quickly. Obstruction of the superior vena cave is a medical emergency and this responds dramatically to radiation. Treatment should be undertaken at once and biopsy delayed until the patient has stabilized. Radiation therapy plays a most important role in the treatment of brain metastasis. In a series of 108 cases reported from the Yale-New Haven Hospital, at least 60% showed improvement in neurologic findings.[5] Patients with the least pretreatment deficit had the best rate of improvement and approximately 12% of the entire group survived for one year.

The question arises whether newly diagnosed cases with widespread disease who are asymptomatic should be treated prophylactically with radiation therapy. At least one study[6] would seem to indicate that early treatment makes little difference in length and quality of survival. Each patient should be evaluated individually and the decision to treat based on the expected length of survival and the nature of the anticipated symptoms. For example, immediate treatment would be advisable for an asymptomatic lytic lesion in a weight-bearing bone. Good palliation has as its aim the improvement of the quality of life rather than prolongation of misery.

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Villous Adenomas and Malignant Villous Tumors of the Duodenum

Case Report and Review of Literature

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ABSTRACT—A case of villous adenoma of the duodenum is presented and six similar cases found in a review of the literature are compared and contrasted to it.

Pathological review of five primary duodenal carcinomas in our institution reveal a predominantly villous pattern. It is postulated that all such carcinomas may well arise from this originally benign tumor.

Villous adenomas of the colon have been a well recognized clinical and pathological entity. Villous adenomas of the duodenum have been virtually unknown.

In the recent past, the authors treated a woman with an adenocarcinoma of the duodenum which appeared to be arising from a typical villous adenoma similar in every respect to those commonly seen in the colon.

Our experience with this case and the subsequent lengthy review of the literature in an effort to find out more about this very unusual tumor motivated the writing of this paper in an effort to save others the difficulties we encountered.

Case Report

A 73 year-old, somewhat confused, white female was admitted to the psychiatric service from a nursing home for further management. At the nursing home, she had manifested mental confusion and some paranoid behavior. This behavior pattern was coupled with recurrent bouts of vomiting. The patient had been at the home for about two years and in good health until the onset of these symptoms approximately a month prior to admission.

After extensive workup (including a negative GI series: Figure 1) showed no physical abnormalities, she was returned to the nursing home on anti-depressant and tranquilizing agents only to be readmitted two weeks later with a severe exacerbation of all her symptoms. Physical examination showed moderate dehydration, but no evidence of severe weight loss. There were no other significant physical findings.

Prior to final decision regarding psychiatric commitment, a second gastrointestinal series was obtained, four weeks after the first series. In this series, an obstructing lesion of the third portion of the duodenum was noted (Figure 2).

After intravenous fluid correction of a mild hypokalemic alkalosis—

Cl^- = 89 (100-110) mEq/l, Na^+ = 139 (130-145) mEq/l

K^+ = 2.7 (4-6) mEq/l, CO^2 = 30 (23-31) mEq/l

attributed to the prolonged vomiting, the patient was taken to the operating room. Exploration revealed an annular lesion of the duodenum invading the serosa with apparent metastases to two adjacent lymph nodes. This was mobile and not fixed to surrounding tissue or to the pancreas. The entire distal duodenum and first portion of the jejunum were resected together with the involved lymph nodes. An end-to-end enteroenterostomy was used to restore bowel continuity.

Her immediate postoperative course was essentially uneventful although her mental status complicated her nursing management and required considerable amounts of intramuscular Thorazine to control her agitation. By the end of the fifth postoperative day, however, she was passing gas and taking a full liquid diet. To our great surprise, her mental status also improved. By the end of the first post-surgical week, she was taking a regular diet and was completely off all tranquilizers. She was discharged back to the nursing home afebrile and asymptomatic on the tenth postoperative day.

She was seen in the office on a monthly basis for the next 15 months. She continued to do well for the first 12 months, well enough in fact to leave the nursing home and marry again. During this time she gained 25 pounds, had no complaints of any kind and looked and acted like an entirely different person. Approximately 13 months after the resection, she noted the onset of vague upper abdominal pains. This pain gradually became more severe, her appetite waned, and she started to lose weight. Vomiting did not recur.

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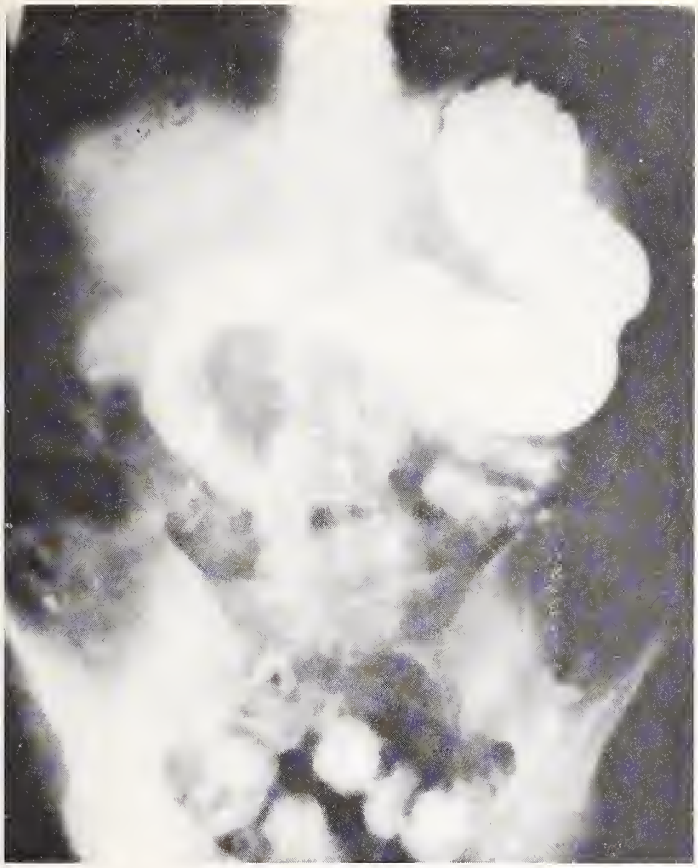

Figure 1
First GI series.

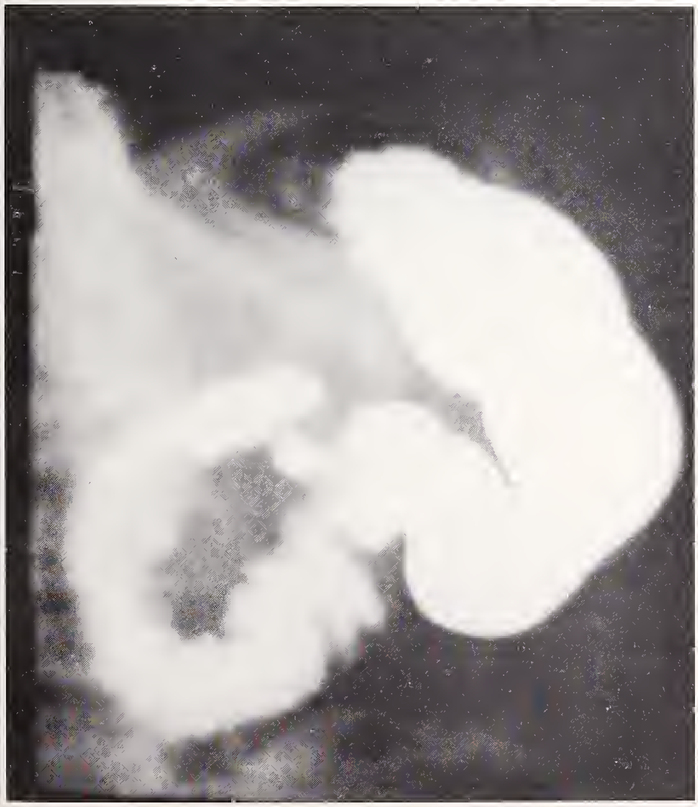

Figure 2
Second GI series showing obstruction of duodenal loop.

Following her 15th monthly visit to the office, she was hospitalized at another institution, on her husband's insistence. After workup there, she was transferred to a different nursing home where she subsequently died, two years from the date of her surgery, presumptively of metastases from her original disease.

Pathological Discussion

The tumor grossly measured 4.5 cm. (see Figure 3) and was elevated and nodular. There was marked stenosis of the bowel due to its presence. The surface appeared finely granular. Beneath the tumor there was induration of the bowel wall. Microscopically, the elevated portion of the tumor showed a villous adenomatous appearance similar to that seen in the colonic lesions (see Figure 4). The villi were composed of hyperchromatic, moderately pleomorphic columnar cells which showed no evidence of secretory activity. The base of the tumor showed invasion of the bowel wall by both small and large glandular elements and also showed areas which

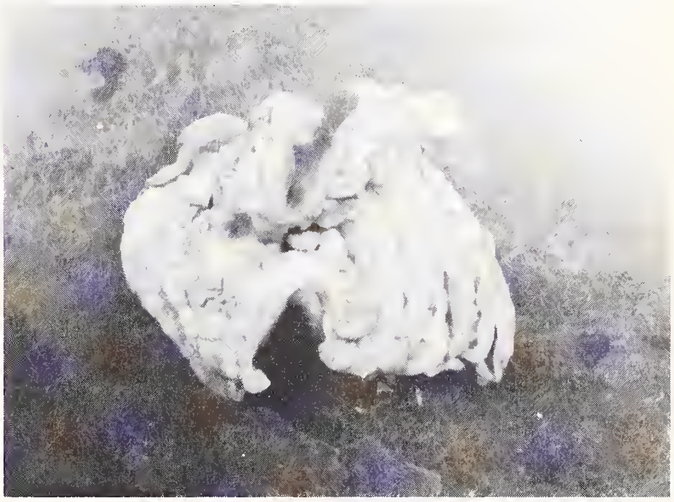

Figure 3
Gross appearance of tumor.

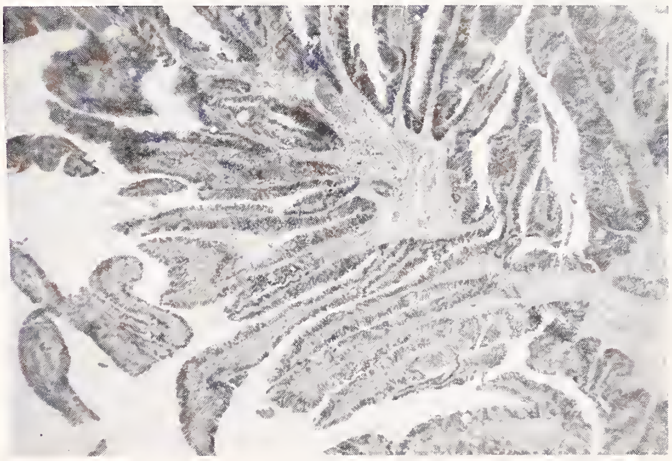

Figure 4
Photomicrograph of elevated portion of tumor showing villous adenomatous appearance similar to colon lesions.

had a villous appearance (see Figure 5). The mucosa of the bowel surrounding the lesion also showed severe atypism, the cells lining the villi being hyperchromatic with no evidence of secretory activity. Two large lymph nodes also showed metastasis by both grandular and villous elements.

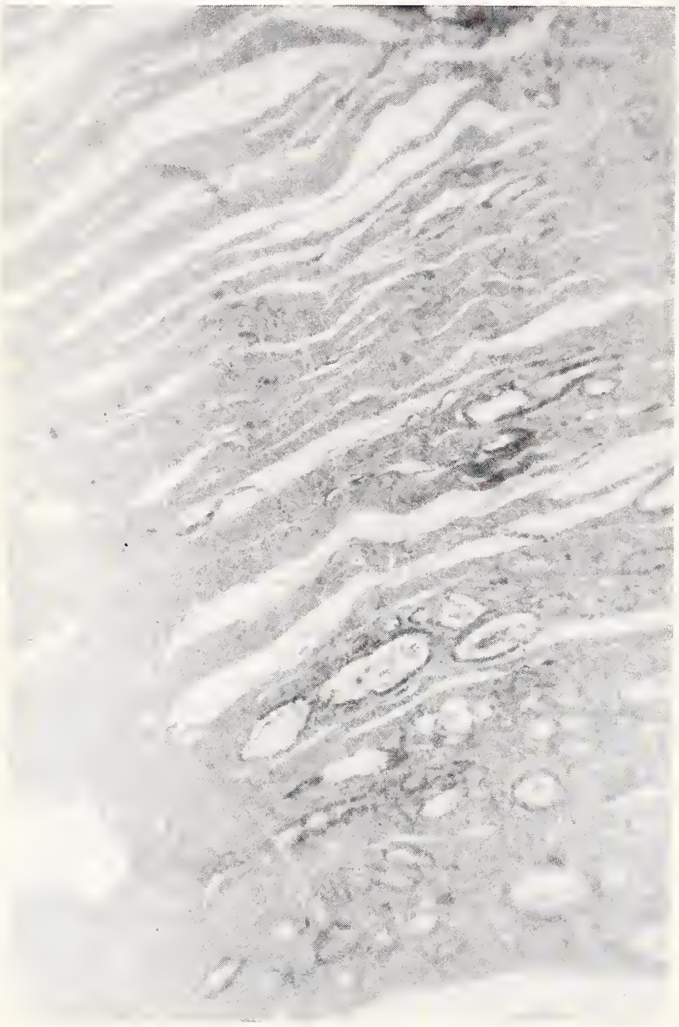

Figure 5

Photomicrograph of base of tumor showing invasion of bowel wall by small and large glandular elements plus areas of villous appearance.

In light of this case, all cases of duodenal carcinoma in our hospital were reviewed. After excluding all cases which could possibly arise from the pancreas or ampulla of Vater, five cases remained, one in the first portion, one in the second portion and the remainder in the third portion of the duodenum. All of these cases showed a predominantly villous pattern, (this is illustrated in Figure 6). All the cases were too far advanced to have been identified as arising in a villous adenoma.

Review of the Literature and Clinical Discussion

After looking at our clinical and pathological material, our interest was definitely aroused. All five cases attributable to a primary duodenal origin microscopically showed a predominantly villous pattern. This most recent case showed a carcinoma arising in the unquestionable villous adenoma. Was it possible that duodenal carcinoma started as a villous adenoma without initial malignant potential?

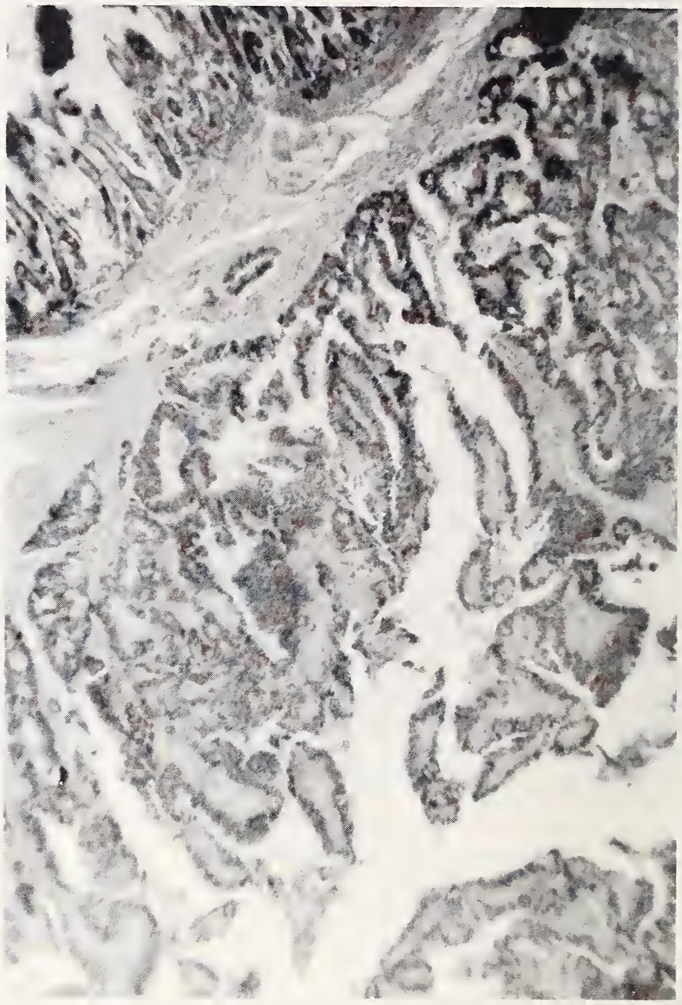

Figure 6

Photomicrograph of duodenal carcinoma showing a villous pattern.

A review of the literature was undertaken. This task was complicated by an unfortunate lack of uniform terminology. The terms "simple adenoma," "papillary adenoma," "polypoid tumors," "villous papillomas" have all been used in addition to the term "villous adenoma." Bremer, et al., in their review of villous tumors of the upper gastrointestinal tract make special mention of the problems created by this particular communications gap.

Bockus, in his treatise on gastrointestinal diseases, states that papillomas and polyps of the small intestine are usually considered to be adenomas, that they are usually small and found as incidental lesions at autopsy. He makes no mention of the existence of villous tumors of the small bowel. Reviews on small bowel tumors by other authors also fail to mention this type of tumor.

Bremer, in his report, limited the tumors described to those resembling in gross and microscopic detail the "villous adenoma" which is commonly found in the colon and rectum. This report has been limited in similar fashion.

In all, six cases have been reported in the literature to date, not including the case in this report. Of these six, two were reported as showing completely benign microscopic characteristics, one showed an in situ carcinomatous change, a third showed evidence of microscopic invasion and the remainder showed varying degrees of overt malignancy. However, the second case of Schorsch is merely a hearsay report. Nevertheless, these five cases and our own represent a full spectrum from complete benignity through frank neoplasm with local and lymph node metastasis.

However, from the existing literature it was not possible to demonstrate a villous pattern in a predominance of duodenal carcinomas, although many authors refer to a papillary pattern or to a villous tendency to these lesions. This is particularly true of British authors.

Clinical Discussion

These tumors are a diagnostic challenge. They occur in an area that until recently has been inaccessible to an instrumental visualization, forcing the clinician to rely on barium meal studies of the duodenum. Our own experience indicates that this is not completely reliable, as our first GI series was reported as negative. Nevertheless, in every other case and on repeat x-rays in our own case this proved to be the conclusive diagnostic tool. Furthermore, two of these cases showed a characteristic feature—the "soap bubble" appearance on the x-ray of this particular lesion due to entrapment of barium particles in the projecting fronds of the tumor.

Table 1

X-RAYS AS DIAGNOSTIC AID

Case 1	Filling Defect
Case 2	Filling Defect with "soap bubble" appearance
Case 3	Filling Defect with "soap bubble" appearance
Case 4	Filling Defect
Case 5	Filling Defect
Case 6	Obstructed duodenum and filling defect on 2nd series

As can be seen from Table 2, these patients can present themselves with obstructive jaundice, with signs of upper gastrointestinal bleeding manifested by melena and anemia, or with nausea and vomiting due to occlusion of the bowel lumen.

Once again, the barium meal should be of considerable aid in delineating these cases from other causes of these conditions and this sort of case underscores the value of this procedure in the work-up of these conditions.

Even at laparotomy, these tumors can be elusive. Two of these cases (4 and 5) had undergone surgery at which the diagnosis had been missed prior to the definitive surgery reported. Speaking from our own experience, this tumor is very soft and difficult to delineate by manual palpation.

Much has been made of the loss of potassium associated with the presence of these villous tumors in the rectum. However, no marked loss of this element was noted in our own case, nor was it mentioned as a feature in any of the other reported cases.

Conclusion

A case history of the carcinoma arising in a villous adenoma of the duodenum is presented and the other five similar cases in the literature are reviewed.

This is an apparently rare tumor and its diagnosis can easily be missed because of its occult location. Patients with this tumor manifest symptoms similar to those with either pyloric obstruction or obstructive jaundice depending on the location of the tumor in the duodenum. In some instances, they can present with upper gastrointestinal bleeding without other symptoms.

Knowledge of the possible existence of this tumor makes possible earlier detection by upper GI series.

It appears to be a benign lesion with a high degree of malignant potential. Indeed, review of our own pathological material—five cases of primary duodenal carcinoma—and review of the cases in the literature raises the possibility that all such carcinomas begin as villous tumors and that this is a pre-malignant lesion.

As such it lends itself to surgical eradication by wide excision in its early stages. It should always be considered whenever one of the three symptom complexes mentioned above develops in a patient.

Table 2

REPORTED CASES VILLOUS ADENOMA OF DUODENUM: CLINICAL FEATURES

No.	*Author*	*Year*	*Age*	*Sex*	*Bleeding*	*Obstruction*
Case 1	Moersch, et al.	1962	67	F	No	Bloating, epigastric distress, eructation
Case 2	Schorsch and Gutierrez	1965	72	M	Melena with severe anemia	None
Case 3	Malmed and Levin	1965	25	F	3-4+ Benzidine test on stool Anemia	None
Case 4	Meltzer, et al.	1966	69	M	No	Nausea and vomiting Obstructive jaundice
Case 5	Meltzer, et al.	1966	60	M	No	Obstructive jaundice
Case 6	Dwyer, et al.	1969	78	F	No	Persistent vomiting

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Emergency Department Testing of Skull Fracture Patients: Minimum Standards and Physician's Performance

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ABSTRACT—Minimum standards of care are being developed in many disease categories. These will become increasingly important as PSRO become established. However, data is not yet available to evaluate patient care in outpatient facilities and, in particular, the emergency department. Yet diagnostic procedures and treatment performed in the emergency department may be the most significant to the patient.

An attempt has been made to establish minimum diagnostic standards for a specific entity commonly seen in the emergency department, namely, skull fractures. A review of 256 consecutive patients with skull fractures was performed and the criteria chosen for minimum diagnostic standards evaluated. It was found that one standard chosen, pupillary and fundoscopic examination, was almost uniformly met while another, radiologic examination of the cervical spine, was only met 30% of the time. This study reveals the need for such minimum standards to be set and points out the difficulty to be expected as each disease entity is evaluated.

Skull fractures are a hazard confronting ever increasing numbers of our population. They are not limited to one sex or to a specific age group. In a recent two-year period, it was reported that there were 3,053,000 recorded cases of skull fracture in the United States and in 1968, there were over 55,000 deaths from automobile accidents in which the principal cause of death was head injury.[1] In Great Britain, head injuries were the leading cause of accidental death in children.[2] Other studies indicate mortality from head injury ranges from 5.8 percent to 10.8 percent, varying with age.[3-6] More-

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over, these studies indicate clearly that the injury causing a skull fracture can, concomitantly cause serious intracranial and cervical spine injuries. Accordingly, the diagnostic testing for such possibilities in the initial period following injury is a matter of paramount concern.[7]

Although the initial period following a patient's injury is the most critical and demands the highest quality of medical care, such care in emergency departments (the usual locus for the administration of initial diagnosis and treatment) may be at times both inefficient and inadequate. One study reports only 25 percent of all emergency patients were provided effectively high quality medical care.[8]

Given the documented necessity for providing excellent initial diagnosis and treatment for skull fracture patients,[1-7] the objectives of this study are as follows:

1. to develop minimal acceptable standards for the identification of intracranial and cervical spine damage in skull fracture patients in the emergency department setting;
2. to determine the extent to which physicians meet these standards;
3. to evaluate the diagnostic outcomes of patients to show the frequency with which intracranial and cervical spine injuries are associated with skull fractures.

Materials and Methods

For the purposes of this study, the following were considered minimal acceptable standards for testing skull fracture patients for intracranial and cervical spine damage in the emergency department setting.

1. Eye examinations for signs of intracranial injury (pupillary size and reactivity and fundoscopic examination);
2. Palpation of the posterior neck for signs of cervical spine injury;
3. Roentgenographic examination of the cervical spine.

In order to fulfill the objectives of this study, a retrospective exploratory study was considered the method of choice. The medical records of a consecutive series of 256 skull fracture patients admitted to the Yale-New Haven Hospital through the emergency department between January 1, 1965 and August 31, 1972, were abstracted prior to coding, key punching, and computer analysis through the standard data text program.

Results

The principal findings of this study are listed under the two types of injury that were postulated would be associated with skull fractures; namely, intracranial injury and cervical spine injury.

Intracranial Injury

1. The emergency department physicians examined almost all (98.8 percent) of the skull fracture patients for signs of intracranial injury as evidenced by a pupillary and fundoscopic eye examination.
2. Almost half (45 percent) of the patients suffered some form of intracranial injury. More than half (56 percent) of these were hemorrhages; 28 percent were concussions; and 11 percent were cerebral lacerations and contusions.
3. Intracranial injury occurred almost as frequently with fractures to bones of the base of the skull as with those of the vault of the skull—44 percent and 45 percent respectively. The frequency of intracranial hemorrhage associated with basilar skull fractures was somewhat higher (56 percent) than with fractures of the vault of the skull (51 percent).
4. Only five of the 256 patients (2 percent) died in the hospital.

Cervical Spine Injury

1. The emergency department physicians palpated the necks of most (89 percent) patients for signs of cervical spine injury.
2. Emergency department physicians ordered roentgenographic examinations of the cervical spine on only 30 percent of the patients.
3. There were no cases of cervical spine injury recorded on the discharge diagnosis summaries (except in a single case which was in contradiction to the radiologic examination report that stated no abnormality was found).
4. The number of cervical spine roentgenograms performed was significantly greater in older patients as compared to younger patients, in patients with more severe or multiple injuries, in patients with signs of intracranial injuries.
5. Out of 228 patients on whom neck palpations were performed, only 73 (32 percent) also had cervical spine roentgenograms. These 73 represented only 28 percent of the total series of 256 patients. Of the remaining 155 patients whose necks had been palpated, but who did not receive radiological examination of their cervical spine, 44 were calssified as patients with severe head injuries. (See Table I).

Discussion

The literature on intracranial and cervical spine injuries associated with skull fractures does not identify any work addressed specifically to the frequency with which physicians actually used any particular diagnostic procedure. However, there is documentation for general characteristics of series of skull fracture cases and for the importance attached to intracranial and cervical spine injuries associated with head trauma.[1 3 5 6]

Studies concerned with the diagnosis of head injuries cite eye manifestations, the level of consciousness, and the timing and duration of post-traumatic amnesia as the principal diagnostic indicators of intracranial injuries. Flamm has traced the historical development of the awareness of the medical profession to the associations between eye manifestations and intracranial and other injuries.[11] Many other studies have described adequately the pathological sequellae of head injuries such as subdural and epidural hematomas and laceration of the brain.[2 6 7 8 10 13] However, it was not until 1837, with the publication of Hutchinson's "Four Lectures on Compression of the Brain" that the mechanism of the dilated pupil was fully explained. Now this mechanism has become generally understood and is recommended for use in diagnosis. In 1970, Goebert commented as follows:

> "Especially in this age of high speed automobiles and even more dangerous motorcycles, the accidental occurrence of epidural hemorrhage is an increasing problem. Its recognition is extremely important; prompt treatment may save the patient's life. We have, therefore, come to recognize a sign of unilateral pupillary dilation as one of the most reliable indications of a neurosurgical emergency. Irreversible damage can occur with prolonged procrastination over operative intervention."[14]

This article explains in detail the various relationships between various eye manifestations and the related types and location of intracranial injuries. Other writers also have dealt with the diagnostic values of eye manifestations in relation to intracranial injuries.[1 6 7 8 10 11 12]

The association of cervical spine injury with skull fracture is not as well documented in the literature as that of intracranial damage. However, those who do cover the subject write with conviction. Devivo and Dodge, comparing cervical spine and skull roentgenograms stated:

> "Cervical spine x-rays are far more important, although usually overlooked. A spinal cord injury, especially at the critical level, may be very serious—in fact much more serious than the head injury if not recognized."

Similarly, Harris reported:

> "In some reported series, 30% of all patients requiring admission to hospitals because of head injury have a significant associated injury . . . One injury may adversely influence the effect of another, giving a cumulative effect . . . Anyone with a head injury should also be considered to have a cervical spine injury which should be especially looked for . . . It is possible to diagnose a spinal cord injury in a person who is unconscious from a head injury."[10]

Tindall and Meyer provide another direct reference citing the importance of examining for cervical spine injury in skull fracture cases.[1] Among the diagnostic procedures they recommended:

> "A complete physical and neurological examination including evaluation of 1) airway, 2) level of consciousness, 3) presence of focal neurological signs, and 4) presence of shock and multiple injuries including spinal cord injury."

In addition to examining eye manifestations and examining the cervical spine by palpation for rigidity or malalignment and roentgenograms, there was one other important diagnostic procedure originally considered as a minimal standard for the evaluation of a skull fracture patient; namely, analysis of level of consciousness and post-traumatic amnesia. This was not included in the present study for two reasons. First, in many cases it is not possible for the emergency department physician to have reliable data. The testimony from the patient, if any is possible, is almost always distorted. In addition, that of eyewitnesses is little better. Secondly, there is some disagreement among knowledgeable physicians as to its significance.[4 9 10 11 12]

Therefore, while considerable research confirms the importance of eye examinations, neck palpation, and radiological examination of the cervical spine in patients with skull fractures, no other studies indicate the extent to which these diagnostic procedures are actually performed. The data in this study show that the eye examination standard was almost uniformly met—253 out of 256—with the possibility that the other three may have been performed, but not recorded on the medical record. This finding confirms that the physicians did associate the possibilities of intracranial injury with skull fracture and did seek through the means of eye examination to identify the presence, and to some degree, the location and the nature of intracranial injury.

Since eye examination as a minimum standard of care is such a well-established part of the diagnostic process for skull fracture patients it would seem desirable to add further procedures representing higher standards of care. For instance, an attempt might be made to define and establish as minimum standards the application of diagnostic procedures relating to level of consciousness of the patient or duration and timing of post-traumatic amnesia.

Neck palpation was the principal means used by the physician in this study to explore for possible cervical spine injury. This was used in 89 percent of the cases. Of the remaining 11 percent of cases, nearly 80 percent were patients with "non-severe" injuries. Thus, the physicians seemed to be applying good clinical judgement since the few patients not tested were those with less severe injuries.

The criteria of roentgenographic examination for patients with skull fractures was not met. In fact, only 30 percent of the patients received the examination. As the results of those examined were all negative, we must question whether this standard may not have been too rigid. On the other hand, even though the incidence of cervical spine injury among skull fracture patients may be small, the potential damage to the cervical spine injury victim can be great. Perhaps instead of a rigid 100 percent standard, the radiological evaluation of the cervical spine should be a provisional standard to be performed when one or more of the following conditions are met:

1. Intracranial injury has occurred.
2. Multiple injuries have occurred.
3. Neck palpation shows rigidity, swelling, tenderness, or any sort of anomaly or abnormality.
4. Mechanism of injury suggests that severe trauma was involved, especially strain or impact on the neck, such as whiplash, rapid acceleration/deceleration type of blows on the head, upper torso, etc.

Table I

CERVICAL SPINE RADIOLOGIC EXAMINATIONS BY SEVERITY OF INJURY OF SKULL FRACTURE PATIENTS ON WHOM NECK PALPATIONS WERE PERFORMED

	Cervical Spine Radiologic Examinations					
Category	*Performed*		*Not Performed*		*Total*	
of Injury	*Number*	*(%)*	*Number*	*(%)*	*Number*	*(%)*
Severe	47	(64)	44	(28)	91	(40)
(%)	(52)		(48)		(100)	
Non-Severe	26	(36)	111	(72)	137	(60)
(%)	(19)		(81)		(100)	
Total	73	(100)	155	(100)	228	(100)
(%)	(32)		(68)		(100)	

In this study if the physician had observed standards defined in this manner, they would have had cervical spine roentgenograms on more than 200 patients rather than the observed 78, as 204 patients had multiple injuries. Also 158 patients were classified as having severe injuries or intracranial injuries or both. Certainly it would seem prudent to perform cervical spine roentgenograms on all such patients. Although the 78 radiological examinations performed produced negative results, it is possible that if an additional 125 or so more of the severely injured patients had been examined radiologically, some cervical spine injury might have been detected.

Clearly in an on-going monitoring system, special attention must be devoted to the question of tests for cervical spine injury if appropriate minimum standards for diagnostic procedures relating to cervical spine injury are to be acceptable. Moreover, in the interests of good patient care and as a method of continuing education and teaching, we believe a monitoring system for physician performance in the emergency department should be given close attention. While admittedly an arduous task it is believed that minimum standards for patient care in this area should be developed and integrated closely with a monitoring system. Hopefully, the results of this study will measure professional efforts in this important area.

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Guy W. Van Syckle, M.D., F.A.C.P.
President

The President's Page

There is a legend that the ghost of Daniel Webster returns now and again to ask the question, "Neighbor, how stands the Union?" If Daniel were to ask the same question of the profession right now, the temptation would be to answer that neither stands very well. After all, we both have been battered from almost all sides for well over a year and never has the state of the art been more dependent on the state of the union. The public immorality uncovered by Watergate has further impaired the credibility of our institutions and present economic policies threaten their very existence. Of more concern is the continuing flow of social, economic and sometimes purely political legislation emanating from Washington which threatens to demolish the whole framework of medical care as it presently exists.

Beginning almost ten years ago with Medicare, Medicaid, and the RMP programs, examples of this kind of legislation have been sending shock waves through the medical community. This same legislation, loosely based on a combination of medical myths, wishful thinking, and carefully researched guesswork, has as a common denominator a thinly veiled hostility to the profession and its health care allies.

Public Law 92-603 containing the PSRO section holds doctors for the first time publicly accountable for the quality, medical necessity, efficiency, and cost effectiveness of the health care they provide. The HMO concept has been embraced by leaders of both parties and we are in the midst of a federally funded and enthusiastically supported five year experimental program. This was all done in the face of well documented studies outlining its poor potential for effective national implementation.

The Emergency Medical Systems Act of 1973 calls for consumer input in emergency care. The law requires that members of the community be part of the planning process and have significant authority in the operational process. This is the first time that this kind of lay participation in medical and hospital affairs has been specifically legislated in a bill.

The Health Manpower Act expires June 30th and Congress is presently debating what changes, if any, are needed. The Senate bill would regulate the supply and distribution of physicians and require that all graduates of health professional schools serve two years in areas where health care is lacking. The administration program would reduce the government role in health manpower and require two years of service only for those students receiving aid during their training. It seems ironic that only a year or so after voting an end to compulsory military service we are now witnessing an attempt by our representatives to make conscripts of our health professionals.

And now, as a further foundation for the impending National Health Insurance Program, comes the National Health Planning and Resource Development Act of 1974. This law will ultimately replace Comprehensive Health Planning, Regional Medical Programs, Hill-Burton and Experimental Health Service Delivery Systems authorities. The implementation of this law will make a mockery of the PSRO legislation and our present efforts to conform to the law.

This gloomy review of the present state of affairs is only an attempt to define reality. While concerned, I am not resigned. We have alternatives and responses available but these are for future issues. If we can unite and prevent further fragmentation of the profession; if we can stay close to our area of competence—the practice of medicine; and if we can identify our policies with the public good, perhaps next year at this time we can reply to Mr. Webster: "It is a troubled profession but it still stands strong."

Guy W. Van Syckle, M.D.
President

Reflections From The Dean's Office

Robert U. Massey, M.D.

In the recent television series, *The Ascent of Man,* many of us, besides being delightfully informed, have come to know better the remarkable man, Dr. Jacob Bronowski, mathematician and philosopher of science, who died shortly after completion of this series.

In 1953, when he was Carnegie Professor at the Massachusetts Institute of Technology, Dr. Bronowski delivered a series of lectures which have since been published in a little book called *Science and Human Values.*[1] They appear as three essays, *The Creative Mind, The Habit of Truth,* and *The Sense of Human Dignity.* The theme of the essays is recapitulated in a short dialogue which he added at the end of the book, *The Abacus and the Rose.* The dominant theme in Dr. Bronowski's words is "that science is as integral a part of the culture of the age as the arts are."[2] It is the theme of *The Two Cultures* of C. P. Snow, the substance of the three century debate between the traditions of science and humanism.

Snow, if I understand him, pleads for bridges between the two traditions to allow for exchange of views, better understanding, greater respect, and perhaps some borrowing of concepts. He allows, however, that the cultures are by now quite separate, perhaps fundamentally so. Bronowski, on the other hand, sees a fundamental unity and that unity lies wholly in the remarkable organ of the mind which has created both art and science. Both the artist and the scientist looking into nature see some aspect of the same vision, and the truth of their created expression of that vision lies in the nearness to experience. "The sanction of experienced fact as a face of truth is a profound subject, and the mainspring which has moved our civilization since the Renaissance."[3]

The scientific method, the "powerful engine" of Bacon, gives us a way of ascertaining the truth, at least in so far as that fits with the innate structures of our own minds. Artistic or poetic assertions also must square with our own experience before we can call them true. The creative mind speaks across time and space to other minds and is recognized. What is *out there,* what is *really true* may be nonsense questions; truth for us must remain forever wholly subjective.

University faculties, especially faculties in schools of medicine, have problems when they attempt to define scholarship. Is scholarship to be confined to those who discover new facts or new relationships and from them create new laws of nature? Can a practitioner be scholarly, or a teacher who draws upon the original creations of other minds? In the humanities unlike the sciences the creators are often not in the schools; rather their scholars are critics and commentators.

This has practical implications for medical school faculties. We rely upon practitioners who devote a portion of their busy days to teaching our students and caring for our patients. Should they not be welcomed to the fellowship of scholars?

Dr. Bronowski helps me to resolve this problem. The act of creation is re-enacted when it is understood: "The act of creation is therefore original; but it does not stop with its originator. The work of art or of science is universal because each of us recreates. We are moved by the poem, we follow the theorem because in them we discover again and seize the likeness which their creator first seized. The act of appreciation re-enacts the act of creation and we are (each of us) actors, we are interpreters of it."[4]

The scientist, teacher, practitioner, and student are, in Bronowski's view, all caught up in the same act of creative intellect and each in his turn may be the original creator drawing together all the others. Creativity has to do with the discovery of relationships which others recognize as true. Creativity and ascertaining truth include, but are greater than scholarship, and are the marks of intellect.

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"For when was honey ever made with one bee in the hive"...

Thomas Hood, *The Last Man*

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Connecticut Medicine

Editorials

Lung Cancer—1975

In 1975, nearly 69,000 men and women in the United States will die from lung cancer. Each year the number of deaths from this disease increases, despite intensive campaigns to curb cigarette smoking and national cooperative programs to devise more effective therapies. Unlike the patient with carcinoma of the cervix, breast, or colon, the patient with carcinoma of the lung can be offered little hope of cure. The grim fact is that 70-75% of patients diagnosed in 1975 will have nonresectable tumors at the time of diagnosis, and less than 10% of all patients with carcinoma of the lung will survive their disease.[1]

Not too many years ago, when the close association between cigarette smoking and carcinoma of the lung was established, it seemed reasonable to expect that people might be convinced to stop smoking if they knew how injurious to their health, and yes, how lethal it could be. What was reasonable five years ago clearly did not come to be for the campaigns by the American Cancer Society and the Surgeon General have had little lasting impact, and cigarette sales today are as great as ever. Given the current inflation/recession economic situation and the resultant increase in the level of national tension, cigarette consumption probably will continue to increase as Americans reach for that handy pack of long white tranquilizers. Stringent regulations to give our cities cleaner air likewise continue to elude us as the demands to conserve energy dictate a relaxation in anti-pollution time-tables at the expense of our environment and our health.

With prospects for prevention of lung carcinoma so poor, and surgery, radiotherapy, or chemotherapy alone so ineffective, is there any cause for optimism? I believe the answer is a cautious "Yes."

In the areas of detection there is already much that can be done.[2] All persons at high risk (cigarette smokers over the age of 45, persons with heavy exposure to asbestos, uranium miners, chromate and arsenic workers) can be encouraged to have periodic screening for lung cancer. Such persons should have PA and lateral chest roentgenograms and sputum cytology examinations (three morning specimens) at intervals of no less than one year and possibly more frequently. Within the next few years, screening techniques may improve greatly. Research in lung cancer diagnosis is currently being directed towards the automation of cytologic examination, a determination of prognostic significance of epithelial atypias, a search for sensitive immunological and chemical markers, and an evaluation of fiberoptic bronchoscopy in patients with positive sputum and negative chest roentgenogram findings. Although clear evidence to substantiate a higher cure rate with earlier detection is not available, and individual tumor biology cannot be ignored,[3] it is not unduly optimistic to presume that discovery of more lesions at an earlier time in their evolution will result in a higher rate of resectability with fewer recurrences and deaths.

In the area of therapy, there is also cause for optimism, cautious though it must be. The studies in oat cell carcinoma (cited by Drs. Marsh and Stern elsewhere in this issue) in which chemotherapy and radiotherapy or surgery and radiotherapy were used in a planned sequence are first generation examples of combined modality therapy which promises more effective treatment of lung cancer in the future. As we continue to learn more about drug scheduling and drug interactions, about stimulation of antitumor immunity (or other non-immune resistance), and about more rational ways to combine chemotherapy and immunotherapy with surgery and radiotherapy in earlier lesions, the prospects for better control and perhaps more cures, are indeed brighter.

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Alexander M. Schmidt and the FDA

The article carrying the byline of Alexander M. Schmidt, M.D., Commissioner of the Food and Drug Administration, in our April issue, is part of an experiment in which this Journal is currently engaged.

We are limited as a state journal in soliciting original manuscripts from executives of the various health related agencies of the federal government. However, we believe that many of the activities of those agencies have a direct bearing on the day-to-day practice of medicine in our state, and that many of those activities are something less than well understood by the very physicians who should understand "not only the national implications" but also the special local, state and regional aspects of them.

Our experiment, therefore, is to see if some procedure can be devised by which we can publish the words of key federal agency executives in areas which have a high level of interest and importance for our physician readers, and then coned down on local aspects of those issues.

We are delighted with the material Commissioner Schmidt provided us in this regard, and his invitation to us to reprint that material in its entirety, or excerpted or abstracted from it. We chose to do the latter, on the entire issue of drug review and approval, from his statement before the U.S. Senate's Health Subcommittee on September 24, 1974. Because these are his actual words, we took the liberty of interpreting his suggestions as permission to acknowledge his authorship, also with his permission. When we use this technique, as opposed to an entire article's being written by such an executive, we shall in a footnote so state—"Abstracted by Editor and Staff."

We now defer to our readers. Are there issues related to the process on drug review and approval that you would like to know more about? Are there some local aspects of those issues which we can direct to some of our Connecticut colleagues for reply, or if necessary, to the FDA's newly established Office of Professional Education for reply? Is this a practical way of considering national issues on a continuing basis? We look forward to your comments.

Fred Fabro, M.D.

Echocardiography

Echocardiography is a new and exciting diagnostic tool, becoming available to all practicing physicians. The technique is non-invasive and harmless, without risk of mortality. Information obtainable from this new procedure, in some cases, eliminates the need for cardiac catherization.

Echocardiography facilitates definite diagnosis of mitral stenosis, degree of severity, based on the presence of calcifications, and suitability of valvular commisurotomy versus valvular replacement. Diagnosis of atrial myxomas is readily obtainable; in some cases, cardiac catherization may not disclose a tumor, while Echocardiography will. Pericardial effusions, idiopathic hypertrophic aortic stenosis, cardiomyopathy, and prolaspe of mitral valve leaflets can all be definitively diagnosed. Diagnosis of pericardial effusions is so firm that further study is unnecessary. Enlargements of the right ventrical, and right ventricular overload conditions can be observed. Likewise, left ventricular overload and elevation of the end diastolic pressure can be concluded from the findings. Detection of congenital heart disease, Tetrology of fallot, atrial septal defects, and Ebstein anomoly, are confirmed by this procedure. Studies on Echocardiography findings of acute myocardial infarction are now being conducted by Drs. Harvey Feigenbaum and Dillon in Indianapolis. They have found, for example, that the intraventricular septum as well as the left posterior wall loses mobility during an attack of angina, and myocardial infarction. Patients with abnormal cardiac stress tests will demonstrate septal motions, reverting to normal with nitroglycerine. Those with normal cardiac stress tests and coronary artery disease may disclose no septal motions secondary to disease of the left anterior decending artery. Aortic stenosis can be ruled out by demonstrating normal aortic leaflets.

In daily practice, Echocardiography is best employed in helping to define heart murmurs, arrhythmias, cardiomegaly, and chest pain. Bacterial endocarditis can also be demonstrated by the presence of leaflet vegitations. More and more information is being accumulated on the usefulness of this exciting procedure, which, although difficult to perform, is easier to interpret. It can be mastered by all practicing physicians. Echocardiography will someday become part of the every day armamentarium of the internist and cardiologist as is the electrocardiogram today.

Siegfried J. Kra, M.D.

An American Look at British Medicine

John C. Marsh, M.D.

The occasion of a sabbatical year in England has given me the opportunity to observe various aspects of British medicine, many of which differ considerably from those in the U.S. The major contrast is that virtually all British physicians are salaried employees of the National Health Service, which came into being in 1948 with an initial annual budget of £150 million but which by 1974 had risen 20-fold. Nevertheless, it is claimed that Britain spends less per capita on health care than any other civilized country in the world. Doctors' salaries are sharply fixed and negotiated with the Government. The number of specialists ("consultants") in a given area is set by the Government's estimate of medical needs for that area. Consultants are allowed to have private patients, and an affluent minority of British citizens (about 2%) choose to go the private route. From the standpoint of the consumer, medical care is guaranteed under the NHS and no one need suffer financial disaster from prolonged hospital bills or doctor bills. Most patients and doctors seem to feel that this basic principle is well worth maintaining, but there are many vigorous discussions about the shortcomings of the system and the need for strengthening it. Advertisements for insurance for private medical care are, however, increasing. The average premium is about $80 per year.

The general practitioner (universally called "GP") is the backbone of the system. Just under half of the country's 50,000 doctors are GP's and do virtually all the non-hospital medicine. With very little exception (in western England there are GP hospitals), the GP does not care for or follow his patients in the hospital but refers them to a consultant. He resumes their care upon discharge. One GP has on his list about 2,400 people, an average which is kept amazingly constant throughout the country. According to some recent figures, the most "overdoctored" area has one GP per 2,224 and the most "under-doctored," one per 2,580.[1] He is theoretically responsible for these patients 24 hours a day. Increasingly GP's practice in groups and in many areas arrange for night call through an agency, which is often staffed by moonlighting junior hospital staff. The average GP's annual salary is $14,000. He is paid $3.80 yearly for each patient on his list and another $3.60 when he renders emergency treatment to a patient not on his list. Only about 0.6% of the average GP's patients are private; they tend either to be older patients, who remember the days before 1948 and pay out of habit or patients who feel they obtain better service. There are a number of rather good postgraduate education programs aimed at GP's; Guy's Hospital Medical School, the first in London to have a Department of General Practice, has just endowed a new chair in this area.

One enrolls with a GP by contacting his office; if a vacancy exists, one is placed on his list. An NHS card with a number is then issued. One has the right to leave a given GP and seek another. Assignments are generally made for geographic reasons. My family and I are enrolled with a GP whose home and "surgery" are close to ours (with an eye to making night calls more easily), although his clinic (in a group) is somewhat farther away. Our GP is in a clinic with five others, and they cover for each other at night and on holiday. House calls are made when thought necessary. The following system for prescriptions has evolved: When we need a refill, we telephone the office and the prescription is left for us just outside the door of the doctor's house. An eye-opener was the fact that about $15 worth of medicine in the U.S. here cost a dollar. A flat charge of $50 is made per item. No automatic refills are given, so that the doctor's office must be called about once a month and the same procedure repeated. The average GP writes about $24,000 worth of prescriptions annually. Since it was decided a long time ago that it would cost more than it was worth to evaluate the citizenship of prospective recipients of health care, living at a particular address is enough to qualify for membership in the NHS. Foreigners may, however, be required to pay hospitalization costs for a pre-existing condition.

The availability of the doctor varies. His secretary does a good bit of screening of incoming calls and requests for appointments. When my son developed pain in his knee and inability to bear weight on it following a vigorous soccer game, I was told it would be six days before he could be seen. When I inquired about an orthopedic referral, I was informed that the GP would have to see him first—sort of a medical Catch-22. However, she opined that if this was in the nature of a traumatic injury, it might be possible for him to be seen in the casualty ward (emergency room) of the nearby general hospital. Consequently, we were seen there by a solicitous Indian resident,

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DR. JOHN C. MARSH, Associate Professor of Medicine and Pharmacology, Yale University School of Medicine; Faculty Research Associate, American Cancer Society; and Eleanor Roosevelt International Cancer Fellow.

who X-rayed the knee, and then by his consultant, also Indian, who seemed quite knowledgeable and very pleasant. Since the offending knee was now staring to feel better, he did what seemed quite reasonable: outfitted us with a brace, crutches, and a follow-up appointment. The entire process consumed about 3½ hours, which is comparable to some of the U.S. emergency rooms I've known.

On another occasion of unexplained, subacute abdominal teenage pain ("abdominal flu"),[2] gradually resolving, we were seen the same day at the GP's clinic. A blood test was ordered, some time and distance away at the hematology lab. of the same general hospital. At this latter visit the GP described himself, somewhat to my surprise, as one of a "dying breed." In his view, young British medical graduates were going into specialties and/or emigrating. According to him, the new GP, on whom the NHS really is based, is being supplied by doctors from other countries, especially India or Pakistan, trained, partially at least, in Britain. On the other hand, in a recent survey of students at Guy's midway through their clinical course, 60% were intending to be GP's.

Complaints of GP's tend to be centered around inability to afford to fix up dreary or dilapidated offices, too little time available to spend with the patient, and, of course, too little money. He is the poorest paid of any European GP's (although the TV special about this gave a misleadingly high figure for American GP's), and it is alleged that he has fallen 15% behind other workers in the two years between April 1972-1974. At this writing an approximately 30% pay rise is on the horizon, with threats of mass resignations if this is not forthcoming. It is worth noting that retail prices rose in Britain 20% during 1974.

Virtually all care of hospitalized patients is by the consultant. There is a good deal of competition for these jobs, and this goal is often not achieved until the age of 40 or beyond, since the number is limited. A man qualifying in a specialty in one part of the country and wishing to practice there may find that the only vacancy in his specialty is in another part of the country. He is paid a maximum of $18,700 annually, but generally less. An oncologist of my acquaintance in a senior position in a cancer hospital is paid $12,800. As Dr. Paul Beeson, former Chief of Medicine at Yale and recently a professor at Oxford, has pointed out, however, the consultant has no overhead for office expenses and will receive a pension at retirement.[3] A third of the consultants also receive cash supplements called "merit awards." Three thousand receive Type "C" awards, worth $3,585 annually, 1,311 receive Type "B" awards, worth $8,425, 453 get a Type "A" award, worth $14,350, and a select 124 get $18,900. The awards seem to be determined upon recommendation of regional committees in a rather non-uniform way, and the names of the recipients have not been made public. Committee members are themselves composed of consultants holding awards. One physician was recently quoted as saying, "The merit award is a political weapon to keep people in line. Doctors won't speak out because they fear they will be overlooked."[4] About half the consultants supplement their income with private practice, the average yearly increment being $4,700. A few, usually surgeons, may double their income. One cardiac surgeon, for example, a subject of a recent television documentary, did this by performing some fifteen extra open-heart operations a year, a far smaller number than he does under the NHS. One surgical consultant, contrasting the amount of time spent seeing patients in the outpatient department, said that on average, he saw one patient every 4 minutes, that they deserved at least 15, and that he spent about 30 minutes with private patients. An item currently under hot dispute is the announced intention of the Government to phase out the 1% of NHS hospital beds which are private, a move announced shortly after the last election in which the Labor Government consolidated its position in Parliament. Private patients may be admitted electively much more rapidly than regular NHS patients, thereby "jumping the queue," a source of great annoyance. The Government has recently offered a new contract to consultants which would make it much more attractive for many to commit themselves full-time to the NHS and give up private practice. Merit awards money would go primarily to these full-time men, and they would be given first crack at extra work. The appeal of private practice would be substantially less, especially for younger men. The consultants' organizations have found the new contract unacceptable and claim support by 80% of their members. At the first of the year, a "work-to-contract" was begun, which means that the letter of the existing contracts is being followed—an average of some 30 hours a week (instead of 50 to 60) being put in by the consultant. The result is a great lengthening of the already long queues for elective hospital admissions. Seven months is the average wait claimed in some areas and about a year for some orthopedic work. At issue is not only money, but also the flexibility of a consultant to carry on some private work and, to be candid, some degree of political bargaining power of consultants as a group. This is the most critical issue that I see in British medicine today, and the outcome is certainly unclear. Negotiations between Mrs. Castle, the main Government official involved, and the consultants have broken down, and the Prime Minister has been asked to intervene, but so far has refused. Tempers and time are short.

What of the house staff or "housemen?" They were recently promised a 40-hour week with overtime payments. Already there are some complaints by junior doctors in such specialties as pathology or radiology because of the lessened opportunities for overtime compared to those with more immediate patient care responsibilities. As mentioned, the wait for consultant positions may stretch on for years, and many housemen are into their late 30's or early 40's. Ironically, some of them make more money than some consultants, who are naturally very unhappy. About 37% of the NHS doctors (66% of the housemen) are from overseas. It is also estimated that about 1/6 of the doctors who qualify here (*i.e.*, graduate from medical school) emigrate. A young houseman, 7 years out of medical school, was recently interviewed on television. His wife, also a doctor, had just had a baby, and he was working as a houseman anesthesiologist and moonlighting at night as a GP to try to make ends meet on $8,000 a year. With a London flat and a car (gasoline is $1.37 a gallon in U.S. terms), it just isn't working, and he is leaving for Canada. A medical school dean in a recent letter in Lancet[5] notes that he is losing key faculty members to the U.S. or Canada at salaries double what they now earn. In his view, the "brain drain" is beginning to escalate once again "with a vengeance." University clinical staff are not eligible for the overtime pay of the NHS, with "devastating effects upon recruitment to academic posts."

Morale, then, among doctors seems particularly low. Hospitals are depicted as being in bad physical shape with no money forthcoming for physical plant repairs or new equipment. Most doctors do support the concept of the NHS. "This is potentially the best health service in the world." "The NHS concept of care from birth to coffin is fabulous, but it's now second-rate."

I am not convinced that the cost of living in Britain is much lower than in the U.S. A small 3-bedroom, 6-room house with a very small yard in our area (London suburbia) runs about $45,000. Food bills, at least for our family, are similar to those in the U.S. Although cars tend not to be as large or to guzzle as much gas, the cost of gasoline more than compensates for this fact.

In talking about low doctors' salaries, it must be kept in mind that they do not have to finance their own education. As in all fields, undergraduate college and postgraduate training is tuition-free, and grants are given for living expenses, depending on financial resources. So one of the arguments for high fees by doctors in the U.S., repaying debts for schooling, is not applicable. The medical schools are of very high quality. They operate with far fewer faculty than most U.S. schools. One interesting change is the gradual proliferation of professorships, which until recently have been limited to the department chairman.

How do British doctors view the U.S.? First, as a land of wealth, but one where patients can be financially ruined by a catastrophic illness and where many doctors make a fortune, far more than they should. The cost of malpractice insurance and the huge lawsuits involving doctors in the U.S. are often mentioned. They feel that U.S. medicine has its problems with Government too, as, for example, the recent political overtones to the change of leadership within the Department of Health, Education, and Welfare, and the N.I.H.

Complaints against doctors in Britain are relatively rare, at least at the official or legal level. About 3% of GP's per year are investigated by the local or regional Executive Councils. In 80% of the cases no breach of rules by the doctor is found. When cases are appealed, 20% of the appeals by doctors are successful, whereas only about 4% of those patients appealing a decision by the Council are upheld. The cost of bringing a "malpraxis" action is high, as in the U.S., and quote a gamble. The brain damage and subsequent death of a young child resulted in the award of less than $25,000 to the parents after several years of litigation. According to the newspaper account, an anesthesiologist was quoted as saying, "It's cheaper to kill than to maim," since damages are awarded on the cost of maintaining the injured party, but death claims are not based on loss of potential earning power. A U.S. surgeon estimates roughly $6,000 annual premium for malpractice insurance by some of his California Colleagues; the $60 paid by surgeons in London was a surprise to him.

When I arrived at the Institute of Cancer Research, I was struck by the necessity of filing rather formidable applications with the Home Office in order to experiment on animals (in this instance, mice). Very strict rules apply with respect to anesthesia, and the technique of bleeding from the orbital sinus commonly used in the U.S. is strictly prohibited. On the other hand, as an oncologist, involved at Yale with evaluation of investigational anti-cancer drugs, I was amazed to learn that there is no requirement for our British colleagues in clinical investigation to secure informed consent from the patient, although there is an Ethics Committee. When we use a new form of treatment or some other form of clinical investigation in the U.S., the protocol has gone, at the least, through an institutional Clinical Investigation Committee (and usually through the N.I.H. and sometimes an inter-institutional cooperative group as well). These committees carefully inspect the plan and insist upon a comprehensive form to be signed by the patient, with witnesses, outlining the nature of the study and its possible benefits and hazards. In Britain, it is presumed that the doctor is a man of integrity, compassion, and skill, and if, in his judgment, a particular treatment should be given, that is his decision. A distinguished professor told me of his 3-day hospitalization to evaluate a metabolic abnormality, with infusions, multiple blood tests and urine collections, with no written consent whatever. He had a general understanding of the purpose of the study as outlined by the consultant, but no detailed description of procedures or hazards was given to him. To me, this contrast between animal and human experimentation is paradoxical.

My wife and I were recently privileged to spend a day visiting St. Christopher's Hospice in southeast London. This is the famous hospital for the terminally ill, most of them with cancer, which has done so much to make more bearable the process of dying, both for the patient and family. Many other places are developing similar institutions, including New Haven,[6] which already has a home-care service. The opening of an in-patient facility in Branford is anticipated sometime in 1976. At St. Christopher's the main accent has been on comfort and pain control. Indeed some patients are able to return home after a brief period in the hospital, although the median stay until death is around 10 days. Pain is controlled by use of analgesics every 4 hours, not on demand but by direct order of the doctor. "The patient does not have to earn his morphine." The most commonly used narcotic is diamorphine (heroin), although a recent study by the Hospice suggests that morphine is equally effective. An attempt is usually made to give it orally, often the so-called "Brompton mixture," which includes diamorphine, cocaine, syrup, chloroform water, and a little alcohol. A phenothiazine syrup is given as well. The dose of the narcotic is adjusted (in the liquid) up or down until pain is completely controlled. Contrary to what some might expect, this does not result in a groggy, knocked-out patient, but in a great degree of relaxation and gratitude. Much attention is paid to the bowels as well, and patients are in a comfortable, friendly setting, with a maximum of attention by all the staff. This was a striking demonstration that these unfortunate patients can be cared for as the *focus* of attention, not pushed off into a corner to die alone, neglected by a frustrated staff that feels that nothing more can be done. Dr. Cicely Saunders, the remarkable founder and director of St. Christopher's, has written a chapter in a new textbook of medical oncology[7] on terminal care that I hope will be read by many readers of this article. In it she defines terminal care ("the time . . . when all active treatment . . . becomes ineffective and irrelevant . . . to his [the patient's] real needs.") She points out that it may also be, sadly, when someone says nothing more can be done and begins to withdraw from the patient. She discusses various criteria for in-patient and out-patient treatment, the relief of pain, the understanding of mental distress, stages of realization of death by the patient, what and who to tell regarding the diagnosis, and the place of religious faith.

I was struck by the fact that the out-patient care proceeds in close association *with* the family GP and district nurse. The doctors at St. Christopher's assume management of patients only in the hospital (as is the case with hospitals generally), serving as advisors to the GP when and if the patient goes home. Rarely do GP's try to avoid the home care of the dying patient. The Hospice home-care team does help them in this task, however, with the strong feeling that it must be a joint effort of *all* aspects of the medical community.

I was interested to find that most cancer patients in Britain are not told their diagnosis, although the spouses are. It was estimated that about 30% of St. Christopher's patients speak freely of having cancer, another 20% talk about their "growth," and the other 50% are in a gray area in which the staff isn't really sure what they know. Patients are told their diagnosis if they ask about it, but are not forced into the knowledge. The staff seemed to feel that, in general, patients in the U.S. are treated with more candor and frankness with respect to the diagnosis of cancer than in Britain. I wonder. Contrary to my previous belief, many patients do not automatically assume that St. Christopher's is a one-way street, a place to go to die, but most know it as a place where they can be cared for because of the particular type of problem that they have. The large size of the London area makes this relative anonymity possible in a way that may be more difficult in a smaller community.

British medicine presents a fascinating mixture of advanced research, teaching and patient care, on one hand, and yet on the other, there are increasingly strong currents of dissatisfaction by the medical profession with respect to their professional independence of action from Government restriction.

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Family Medicine: Hartford Hospital and the University of Connecticut

The University of Connecticut School of Medicine this July will nearly triple the number of family practitioners in its residency program. The expansion has been made possible by Hartford Hospital's agreement to take six UofC residents in family medicine on July 1, according to Dr. Alexander Berger, M.D., head of the medical school's family medicine division.

The school now has six residents in training in the relatively new specialty. All began their three-year programs last July and all are based at Saint Francis Hospital. In July, the number at Saint Francis will increase to 10. The six Hartford Hospital slots will bring the total of UofC family medicine residents to 16.

Present plans call for another increase in mid-1976 to 22 (12 at Saint Francis and 10 at Hartford Hospital) and in mid-1977 to 24 (12 at each hospital). In addition, the UofC medical school is involved with a similar but separate family medicine program at Middlesex Memorial Hospital. Dr. Berger is serving as its acting director until a permanent one is found to replace one who left the program some months ago. The Middlesex program now has five residents in it. It will have 12 in July.

Dr. Berger said he was pleased with Hartford Hospital's joining in the UofC family medicine program. "It opens doors to a superb teaching hospital," he said, "and will provide valuable interactions with Hartford Hospital's house staff and specialty attending physicians."

Over their 36 months of post-doctoral, graduate training, family medicine residents serve rotations through the different clinical services at their base hospitals. Each will spend part of an inpatient rotation in pediatrics and medicine at the UofC Health Center's John Dempsey Hospital in Farmington.

In addition, the resident physicians also man UofC's Family Medicine Office in Farmington, seeing patients of all ages with all kinds of problems, emotional as well as physical, and treating them as a family practitioner does in private practice.

At last count, the Family Medicine Office was taking care of 500 patients from about 250 families. The patients are mostly from the Farmington Valley and surrounding communities.

Family practitioners have been recognized as specialists since the late 1960s and require graduate training, as specialists usually do. A newer version of the family G.P., or general practitioner, they serve as primary physicians along with internists and pediatricians.

The Case for Treating Hypertension and the Connecticut High Blood Pressure Program

Adrian M. Ostfeld, M.D. and David D'Atri, Ph.D.

Information provided by life insurance studies convincingly shows a progressive rise in mortality with each increment in blood pressure.[1] The excess mortality is primarily a result of increased cardiovascular, cerebrovascular and renal disease. The value of hypotensive drugs in the treatment of severe and malignant forms of hypertension in which congestive heart failure, retinal deterioration and renal failure commonly occur has been well demonstrated.[2-6] More recently controlled clinical trials have demonstrated the value of lowering blood pressure in reducing the complications of essential hypertension. These trials are summarized here.

To examine the feasibility and value of maintaining patients with essential hypertension on effective long-term hypotensive therapy, Wolff and Lindeman[7] completed a double blind study utilizing 87 out-patients in the Baltimore City Hospitals Hypertension Clinic. The patients were predominantly Black and the period of observation was 2 or more years. Patients were placed randomly on either hypotensive drug therapy or matched placebos. Nineteen among 42 patients in the placebo group experienced a major complication of hypertension, reversed in all but one case by appropriate medication. There were 6 major complications among the 45 patients receiving medication. The major complications included stroke, myocardial infarction, congestive heart failure, encephalopathy with papilledema, and uremia.

The Veterans Administration (V.A.) Study, organized by Freis and co-workers, was a prospective, randomized, double-blind therapeutic trial among men with an average age of 51 years. Selected for the study were patients with pretreatment diastolic blood pressures of 90 through 129 mm Hg. Details of the study design and results have been published in two reports.[8 9] A brief resume follows:

The eligible study population was limited to men with diastolic pressures averaging 90 through 129 mm Hg on the fourth through sixth days of hospitalization. Patients were excluded if they had severe hypertensive complications, if secondary hypertension was present, or if there were severe concurrent diseases, drug sensitivity, obstacles to frequent follow-up visits, doubtful patient compliance or preference by patients for care by their private physicians. For several months preceding randomization and initiation of the trial, adherence to a placebo regimen was assessed and patients were excluded whose blood pressure values were outside the range of 90 to 129 mm Hg. The basis for classifying patients in either a 90-114 or 115-129 mm Hg diastolic blood pressure group was the averaged blood pressure level at the last two pre-randomization clinic visits. A total of 523 patients were randomized into placebo and treatment groups: 143 subjects having diastolic blood pressures of 115 through 129 mm Hg, and 380 subjects having diastolic blood pressures of 90 through 114 mm Hg. Pharmacologic treatment consisted of combinations of hydrochlorothiazide, reserpine, and hydralazine.

In the higher blood pressure group (diastolic BP 115-129 mm Hg), the difference in outcome between the treated and control groups was so great, and the incidence of morbid events in the control group so high, that the investigators judged it necessary on ethical grounds to terminate the study prematurely and place the placebo group on active therapy. These events were summarized as follows by the authors.

Twenty-seven severe, complicating events developed in the placebo-treated patients as compared to two in the active group. Four deaths occurred in the placebo-treated group and none in the actively treated patients. Other complications in the placebo group included grade 3 or 4 hypertensive retinopathy, congestive heart failure, increasing azotemia, transient ischemic attacks, cerebral thrombosis or hemorrhage, myocardial infarction and severely elevated blood pressure. Major complications in the active-treatment group were one cerebrovascular thrombosis and one case of multiple drug toxicity.

Longer observation was required to demonstrate the effect of treatment for men with diastolic pressures in the range of 90 through 114 mm Hg. Of that experience the investigators reported:

The estimated risk of developing a morbid event over a five-year period was reduced from 55% to 18% by treatment. Terminating morbid events occurred in 35 patients of the control group as compared to 9 patients in the treated group. Nineteen deaths related to hypertension or atherosclerosis occurred in the control group and 8 in the actively treated group. In addition to morbid events, 20 control patients developed persistent diastolic levels of 125 mm Hg or higher, a finding never observed

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in the actively treated group. Treatment was more effective in preventing congestive heart failure and stroke than in preventing coronary heart disease.

Detailed reports of side effects are still to be presented. However, the authors report that "dosage adjustments frequently were required because of hypotensive and other symptoms," that there were "two patients lost to protocol because of drug toxicity," and that "administration of either reserpine or hydrochlorothiazide or their placebos was withdrawn because of side effects in 29 patients."

It should be emphasized that the present study dealt with a selected population. Many uncooperative patients were identified and eliminated from the trial on the basis of pill counts, urine fluorescence test results, and irregularity of clinic attendance during a prerandomization observation period. Treatment, obviously, would not have been as effective in a group of patients less carefully selected with regard to their desire to cooperate. The population was further limited in that it excluded women and patients with labile hypertension whose diastolic blood pressures averaged lower than 90 mm Hg during the fourth through the sixth day of hospitalization. Finally, the incidence of morbid events in the group below age 50 was relatively low. Further studies are needed to evaluate the effectiveness of treatment in the elderly, in labile hypertension and in the prevention of atherosclerotic complications, particularly coronary heart disease. Such studies will require larger numbers of patients who can be followed for long periods of time.

Within the limits defined by this study, however, the data leave little doubt that antihypertensive drug treatment is beneficial. The present results together with those previously reported in patients with initial diastolic blood pressures of 115 through 129 mm Hg indicate clearly that the higher the level of blood pressure the greater the degree of benefit of such therapy. Certain complications such as congestive heart failure, hypertensive neuroretinopathy, strokes, and renal deterioration were reduced or eliminated in the treated patients. In addition, treatment prevented elevation of diastolic blood pressure to levels where the risk of developing hypertensive complications is greatly increased.

The availability of such treatment to all citizens of Connecticut requiring it would improve immeasurably the health and life span of those citizens. More than half of all strokes could probably be prevented and eye damage, heart failure and kidney failure markedly reduced. Taking a look at the stroke problem alone, let us try to calculate the benefits of treatment. There are in the United States, about 750,000 strokes each year, 250,000 of which are fatal.[10] Comparable figures for Connecticut are 11,250 strokes per year with a third of them fatal. Treatment of most of our citizens with high blood pressure could prevent 6,000 strokes and 2,000 stroke deaths per year, as well as reduce markedly the number of our neighbors and friends who lose their eyesight and die of kidney or heart failure.

The Connecticut High Blood Pressure Program

Growing out of the results of these clinical trials, the Connecticut High Blood Pressure Program was initiated in 1974 to reduce morbidity and mortality from hypertension and its complications in the state. Funded by CRMP, the goals of the program have been: 1) to set up a network for patient education and physician information and 2) to screen as many persons as possible for high blood pressure followed by systematic referral to sources of treatment that have usually agreed in advance to accept such referrals. The sources of treatment for referred patients are principally private physicians but include hospital clinics, a physician based community health organization and two health centers. All are in Connecticut.

Organizations participating in the program of education, screening and referral are:

1. The Danbury Hospital
2. The Norwalk Hospital
3. The Stamford Health Department
4. The Valley Health Department (Ansonia, Derby and Shelton).
5. Community Health Services of Hartford.
6. The Connecticut Red Cross
7. The Connecticut Heart Association and its seven chapters.

In addition to published results of treatment, the rationale for the program rests on these principles:

1. High blood pressure is in large part a disease without symptoms and therefore, commonly undetected among the citizens of Connecticut.

2. Even persons on treatment are sometimes not well managed either because they fail to understand the importance of taking drugs daily for years or because they have been instructed by their physicians to stop treatment when other physicians would have preferred to continue treatment.

3. Based on nation-wide data, we have inferred that there are more than 300,000 hypertensive persons in Connecticut[11] (B.P. equalling or exceeding 160/95 on repeated measurement). About half of these hypertensives are probably unaware of their blood pressure problem and, feeling well for the most part, are unlikely to consult a physician.[12]

The results of the program may be summarized in this way. By February 1, 1975, about 110,000 persons in the State have been screened. Twenty-one percent of these persons had high blood pressure.* Among those hypertensive when screened, about 55% knew it and 45% didn't. The prevalence of hypertension was (surprisingly) equal among Blacks and Whites, 21%, and substantially lower among Puerto Ricans, 13%. Of those referred to treatment, about 65% actually went. Women were much more likely to seek care after referral than men. Among known hypertensives not on treatment at the time of screening, 40% had stopped medication because they reported that their physicians had told them to do so. Discontinuing medication on their own or never taking it in the first place was the second most important reason for failure to maintain therapy. Drug toxicity and drug costs together accounted for less than 6% of all treatment failures. (With worsening economic conditions, drug costs may become a more important reason for inadequate treatment.) About 70% of those referred as hypertensive had blood pressures in the hypertensive range after referral. In view of the variability of blood pressure, this was a strikingly positive result.

There are certain limitations to be placed on the interpretation of these results. First, the persons screened represent only those who got in line to have their blood pressures taken at screening sites in hospitals, health departments, shopping centers, churches, health fairs, schools and factories. This group is not necessarily representative, in its blood pressure readings, of all the citizens of Connecticut. The reasons given for discontinued treatment are based on the responses of the screenees and may be partially inaccurate. Finally, the results cited are preliminary and will be presented later with greater precision and detail.

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**These figures suggest that there are more than 300,000 hypertensive persons in Connecticut.*

The National Health Planning and Resources Development Act of 1974

Summary and a Brief Comment

Orvan W. Hess, M.D., F.A.C.O.G., F.A.C.S.

On January 4, 1975, President Ford signed into law, the "National Health Planning and Resources Development Act of 1974," which was passed by Congress on December 20. The stated purpose of P.L.93-641* is "to assure the development of a National health policy and of effective State and area health planning and resources development programs and to authorize financial assistance for the development of resources to further that policy."

This massive legislation has far-reaching significance which should be carefully studied by all those interested in health affairs. It is believed by many to have a potential for even greater impact on the nation's health care system than other legislated major health measures, such as Medicare (Title XVIII) and Medicaid (Title XIX). The law was felt by its sponsors to be a necessary step to prepare the way for enactment of a National Health Insurance Program.

Approving, in effect, a certificate of need for health system reform, and "recognizing the magnitude of the problems and urgency placed on their solution," Congress based its action on the following findings:

> (1) The achievement of equal access to quality health care at a reasonable cost is a priority of the Federal Government.
>
> (2) The massive infusion of Federal funds into the existing health care system has contributed to inflationary increases in the cost of health care and failed to produce an adequate supply or distribution of health resources, and consequently has not made possible equal access for everyone to such resources.
>
> (3) The many and increasing responses to these problems by the public sector (Federal, State, and Local) and the private sector have not resulted in a comprehensive, rational approach to the present—
>
> (A) lack of uniformly effective methods of delivering health care;
>
> (B) maldistribution of health care facilities and manpower; and
>
> (C) increasing cost of health care.
>
> (4) Increases in the cost of health care, particularly of hospital stays, have been uncontrollable and inflationary, and there are presently inadequate incentives for the use of appropriate alternative levels of health care, and for the substitution of ambulatory and intermediate care for inpatient hospital care.
>
> (5) Since the health care provider is one of the most important participants in any health care delivery system, health policy must address the legitimate needs and concerns of the provider if it is to achieve meaningful results; and, thus, it is imperative that the provider be encouraged to play an active role in developing health policy at all levels.
>
> (6) Large segments of the public are lacking in basic knowledge regarding proper personal health care and methods for effective use of available health services.

National Health Priorities

The Congress further finds that the following items deserve priority consideration in the formulation of national health planning goals and in the development and operation of Federal, State, and Area-wide health planning and resources development programs:

> (1) The provision of primary services for medically underserved populations, especially those which are located in rural or economically depressed areas.
>
> (2) The development of multi-institutional systems for coordination or consolidation of institutional health services (including obstetric, pediatric, emergency medical, intensive and coronary care, and radiation therapy services).
>
> (3) The development of medical group practices (especially those whose services are appropriately coordinated or integrated with institutional health services), health maintenance organizations, and other organized systems for the provision of health care.
>
> (4) The training and increased utilization of physician assistants, especially nurse clinicians.
>
> (5) The development of multi-institutional arrangements for the sharing of support services necessary to all health service institutions.
>
> (6) The promotion of activities to achieve needed improvements in the quality of health services, including needs identified by the review activities of Professional Standards Review Organizations under part B of Title XI of the Social Security Act.
>
> (7) The development by health service institutions of the capacity to provide various levels of

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*Public Law 93-641, 93rd Congress, S. 2994, Jan. 4, 1975, an amendment to the Public Health Service Act.

care (including intensive care, acute general care, and extended care) on a geographically integrated basis.

(8) The promotion of activities for the prevention of disease, including studies of nutritional and environmental factors affecting health and the provision of preventive health care services.

(9) The adoption of uniform cost accounting, simplified reimbursement, and utilization reporting systems and improved management procedures for health service institutions.

(10) The development of effective methods of educating the general public concerning proper personal (including preventive) health care and methods for effective use of available health services.

With these priorities in mind, the Secretary of H.E.W. will issue, within eighteen months after the enactment of Title XV, guidelines of national health planning policy and goals. He will describe standards for appropriate supply, distribution and organization of health resources.

In order to carry out the provisions of the law, there is to be established in the Department of Health, Education and Welfare, a *National Council on Health Planning and Development* to advise and make recommendations to the Secretary with respect to (1) the development of national guidelines (2) implementation of the program (3) an evaluation of new medical technology for the organization, delivery and distribution of health care services. This Council will be composed of fifteen members: three (non-voting) from Federal departments, plus additional (voting) members appointed by the Secretary. Not less than five shall be persons who are not providers, not more than three shall be officers or employees of the Federal Government, three from the governing bodies of Health Systems Agencies and three from the members of the Statewide Health Coordinating Council.

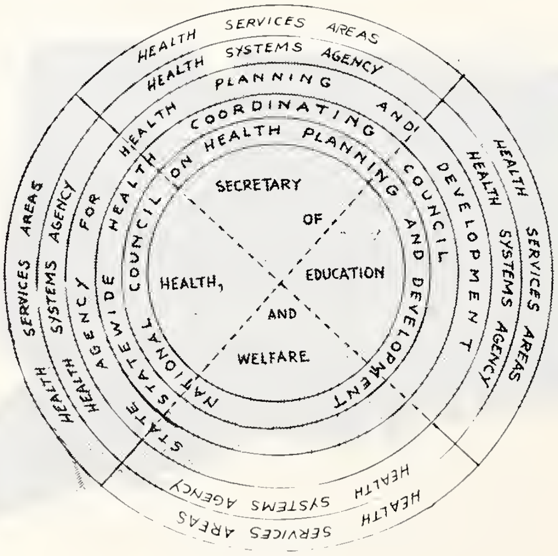
HEALTH SERVICES AREAS
HEALTH SYSTEMS AGENCY
STATE AGENCY FOR HEALTH PLANNING AND DEVELOPMENT
STATEWIDE HEALTH COORDINATING COUNCIL
NATIONAL COUNCIL ON HEALTH PLANNING AND DEVELOPMENT
SECRETARY OF HEALTH, EDUCATION AND WELFARE
HEALTH SYSTEMS AGENCY
HEALTH SERVICES AREAS
HEALTH SYSTEMS AGENCY
HEALTH SERVICES AREAS
HEALTH SYSTEMS AGENCY
HEALTH SERVICES AREAS

Figure 1

Organization of Health Agencies and Councils designated under the National Health Planning and Resources Development Act of 1974.

Health Systems Agencies

On February 27th, Governor Grasso was notified by the Secretary that, by May 3, 1975, Connecticut must delineate *Health Service Areas* for recommendation as regions suitable for the establishment of *Health Systems Agencies*. Each Health Service Area shall be a geographic region appropriate for effective planning and development of health services, have a population of not less than 500,000 or more than 3,000,000 and be coordinated as far as practical with the boundaries of the Professional Standards Review Organizations. Health Systems Agencies (HSA) are to be designated within one year, in consultation with the Governor, from applications which must describe a plan and contain assurance of capability to carry out the prescribed functions. Briefly, an HSA may be a non-profit corporation, a public regional planning body, or a unit of local government having a staff of specified size and a governing body whose membership is composed of a majority (not more than 60%) of consumers of health care. The remaining members will represent multiple disciplines, among whom not less than one-third must be direct providers. Among other duties, this body will be responsible for establishing (1) the health systems plan, (2) for submitting an annual implementation plan, and (3) approving grants and contracts deemed necessary for these purposes.

Health Systems Agencies are designated for the state for the following purposes:

(1) improving the health of residents of a health service area,

(2) increasing the accessibility (including overcoming geographic, architectural, and transportation barriers), acceptability, continuity, and quality of health services provided them,

(3) restraining increases in the cost of providing them health services, and

(4) preventing unnecessary duplication of health resources. Each health systems agency shall have as its primary responsibility the provision of effective health planning for its health service area and the promotion of the development within the area of health services, manpower, and facilities which meet identified needs, reduce documented inefficiencies, and implement the health plans of the agency.

(5) coordinating its activities with each Professional Standards Review Organization.

Annually the HSA shall establish a health systems plan (HSP) and an implementation plan (AIP) to be submitted to the State Agency. The agency is empowered to make grants and enter into contracts with individuals, public, and non-profit entities to assist in planning and developing projects necessary to achieve the formation and goals of the health system described in the HSP. Financial support will be provided from the Area Health Services Department Funds authorized by the Act.

State Health Planning and Development Agency

A *State Agency,* selected by the Governor, will be designated to administer the State Program which shall conduct planning activities and implement the State health plan and plans of the Health Systems Agencies. The State Agency will prepare annually, a preliminary State health plan, incorporating the area HSP's in a manner which will deal effectively with the statewide health needs, for submission to the *Statewide Health Coordinating Council* for review. The State health plan must meet the approval of the Secretary. The State Agency will have many additional functions including the administering of a certificate of need program applying to all new health services, facilities and organizations proposed within the state, and the review of applications for grants by the HSA's.

The Statewide Health Coordinating Council (SHCC), which will advise the State Agency, is composed of no less than sixteen representatives appointed by the Governor from members of the Health Systems Agencies. No less than one half shall be consumers of health care. In addition, the Governor may appoint elected public officials as she deems fit but not to exceed 40 percent of the total membership.

Since provision of quality health care with maximum effectiveness requires continuing conduct of research, statistical studies, and analysis offering new approaches, methodologies and standards, the Secretary of H.E.W. shall, by grants or contracts, aid both public and private non-profit entities in developing at least five centers for multi-disciplinary advice and assistance for health planning and resource development appropriate to the Act.

Finally, to finance the program, Congress has authorized to be appropriated $25,000,000 for fiscal year ending June 30, 1975, $75,000,000 for fiscal year ending June 30, 1976, and $120,000,000 for fiscal year ending June 30, 1977.

Summary

Having proclaimed its version of health priorities for the nation, Congress has enacted a law (P.L.93-641) calling for the establishment of organized Federal-State-Area-wide Systems for health planning and, to a limited extent, implementation of methods for achieving its goals under Government supervision. In a tiered arrangement, entities (Agencies and Councils) at local, state and federal levels have been assigned well-defined authority and responsibility (Title XV). Each Health Systems Agency in the network, established and funded by the Act, will gather data on health needs at the local level (Health Service Area) and formulate its Health Systems Plan and an Annual Implementation Plan within guidelines and standards provided by the Secretary.

A single State Agency, selected by the Governor, will review and coordinate these individual HSA recommendations, and with the aid and supervision of a Statewide Health Coordinating Council, formulate a State Health Program (SHP). This program will, in turn, be reviewed by the National Council on Health Planning and Development and must be approved by the Secretary of H.E.W. prior to its implementation.

The new program will replace Comprehensive Health Planning and Regional Medical Programs. Functions previously carried out by the Hill-Burton facility construction authority will be assumed in accordance with guidelines of the Health Resources and Development Program (Title XVI).

Comment

The Profession and the Citizens of the nation have witnessed legislative "bills" dealing with national health affairs which appeared "on the horizon," were introduced into committees, debated, revised, amended and finally voted into law by Congress (i.e. Medicare, Title XVIII and Medicaid, Title XIX). Constantly on the alert for such actions and desiring to participate, nevertheless, adoption of P.L. 93-641 by Congress and the signing of the Health Planning and Research Development Act of 1974 by President Ford, as the possible framework for a "phase-in" of a National Health System, came as a surprise to many.

Although this piece of legislation is carefully constructed, it deserves in-depth scrutiny by the Profession and the Public since it portends significant change in emphasis on certain health priorities and in methodologies designed to ensure the achievement of goals elected to be in the best interest of the nation. Already, deficiencies in the legislation are claimed by some critics. In fact, the American Medical Association has seriously questioned the constitutionality of the Law.

It is noted that in recent years, an exceptional amount of health planning and some measures of implementation have taken place as promulgated under Regional Medical Programs (originally known as Heart, Cancer and Stroke Act) and Comprehensive Health Planning Agencies. Across the country, these programs have served to provide experience and to produce voluminous reports giving an insight into special needs for the provision of quality health care and the effectiveness of methods devised to accomplish their goals. For this reason, the requirement of the Act that each local Health Service Agency gather data once more to document the needs for health services, manpower and facilities seems to some to be a duplication of questionable necessity. Fully recognizing that differences exist in health care and delivery needs for rural and urban communities, it is argued that these can be determined in Connecticut without the designation of an unwieldly number of service areas.

The Law demands that the membership of the planning groups at the local level, as well as governing bodies and evaluating councils at the state level, shall consist of more than a majority of consumers, while the Profession, with understanding expertise in medical affairs with both short and long-range implications, has a minority representation. The desirability of consumer participation in the process of determining what Society needs, what it wants and what it can afford is not denied. Yet, the question is raised with respect to possible action by a numerically unbalanced membership when medical decisions of consequence, free from political overtones, are required?

Still others are disturbed by the lack of representation of our educational and research institutions which are the time-honored bulwark of continuing education and advances in medical treatment. The Act mandates that "they not be, or operate, a Health Systems Agency." Can we afford to silence the voice of these major resources of wisdom and manpower which are an essential part of the health community?

There is anxiety, also, concerning to what extent the motivation of our voluntary agencies, civic and industrial groups, as well as the hundreds of thousands of members who serve voluntarily in national, state and county professional organizations with laudable humanitarian interests, who have made such important contributions in health affairs, can be preserved? More than ever, wise volunteer leaders are required for timely action for the benefit of all concerned.

The new Law has weaknesses and gaps which deserve further attention. With time and money, errors may be corrected and improvements made in line with changing conditions. In general, the Act is a well-designed product of the intense study and effort which has taken place during the last decade to devise a framework for improved organization and delivery of health care which, in this instance, is oriented around planning at Health Service Area levels. Major responsibilities are delegated to the State for the coordination and implementation of the HSA's emerging recommendations.

Since P.L.93-641 is now the Law, it appears to be in the best interest of all concerned, for members of the Profession to become involved in this early phase. They should seek greater representation on legislated agencies and councils and participate in the effort to correct the mistakes and strengthen its good points.

Human-Semen Banking: Implications for Medicine and Society

Mark S. Frankel, Ph.D.

The concept of human-semen cryobanking—the freezing and preservation of human-semen at low temperatures—can be traced back to 1866,[1] but its implementation on a practical and commercial basis is a more recent phenomenon. While in 1969 there were fewer than ten human-semen banks in the United States, by the end of 1973 the number had grown to sixteen, including three major commercial banks with a combined total of seven branch offices. This rapid increase can be attributed primarily to two reasons. First, with the heightened popularity of vasectomy as a means of birth control, many men have sought some type of "fertility insurance" by freezing their semen for possible later use. Second, there has also been an increase in demand by infertile couples, who represent about 30 percent of all marriages in the United States, for semen to be used for artificial insemination. In the case of a husband's infertility, which accounts for approximately 40-50 percent of all infertility among married couples in the United States, a "donor's" semen may be used for insemination independent of time and place. Semen cryobanking has several other potential uses: to collect and centrifuge oligospermic (deficient sperm count) specimens from the husband for eventual insemination in concentrated form; to collect the semen specimens required to develop techniques to separate male- and female-producing sperm so that couples might predetermine the sex of their child; for selective breeding; for fertility "protection" for men who, because of exposure to radiation or certain medical procedures, may become sterile; and for the study of normal physiology. Furthermore, semen banking has an effective and longer history of use in the breeding of livestock. For example, in 1960 two thirds of the dairy calves born in this country were sired through artificial insemination and the ability to freeze and store semen will undoubtedly increase the volume of such breeding. Such use has led to a better quality of beef which would not have been realized under normal mating conditions.

The most common technique for freezing and storing human semen is in liquid nitrogen at -196.5°C.[2] While the fertilizing capacity of frozen semen has generally been found to be approximately 2/3 of that expected when fresh semen is utilized, semen frozen and stored at -196.5°C can retain enough of its fertilizing capacity to make pregnancy possible. Published reports document over 500 normal births resulting from the clinical use of frozen semen.[3] The results further suggest that the use of frozen semen does not increase the incidence of defects in pregnancy or in the progeny.

Despite these apparent successes, however, the American Public Health Association has recently challenged the unrestricted use in clinical practice of semen frozen for more than three years. The Association has warned that "the biologic potency and genetic adequacy of human sperm which has been frozen and stored over a protracted period of time and then thawed remains to be established." Since the total number of reported pregnancies resulting from inseminations with frozen semen stored longer than six months is relatively small, one should indeed be cautious in assessing the long-term cryopreservation capacity of human semen. Such doubts also suggest the need for greater public accountability by human-semen cryobanks and underscore the importance of assuring that individual and societal interests, however they may eventually be defined, are adequately protected. In this essay, I shall discuss briefly some new dimensions which human-semen cryobanking introduces (or may introduce) into medical practice and the consequences which might ensue.

Substitute For Adoption

One application of frozen-semen banking is to provide a more readily available and acceptable alternative to adoption for infertile couples. Prior studies have found that most couples using artificial insemination prefer it to adoption.[4] It appears that artificial insemination, more than adoption, can satisfy a woman's psychological drive directed toward bearing children. Adoption, then, can never be regarded as a fully adequate substitute for maternity. This raises the question of what consideration is to be given to the welfare of the "hard-to-place" child for whom it has been virtually impossible to find a home, even without the additional competitive pressures exerted by an increased demand for frozen-semen banking? These difficulties in placing some "adoptable children" warrant additional consideration in light of semen banking's emerging capability. It may well not be in society's best interest to strive toward one hundred percent fertility in married couples.

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Vasectomy Insurance

There is a growing recognition of a relationship between the interest in vasectomy, the storage of frozen semen, the growth of commercial frozen-semen banks and population control. The possibility of future fertility through the freezing and storage of semen may encourage some men to undergo a vasectomy in order to regulate the number of their progeny. This approach, however, has been challenged by the National Medical Committee of Planned Parenthood-World Population. Because of what it considers to be the highly experimental nature of human-semen cryobanking, the Committee has argued that "the promise of fertility insurance to be achieved by storing semen may be misleading. Moreover, it may lead to the persuasion of immature or poorly motivated individuals to undergo vasectomy." Since many men may use frozen-semen banking as a means of trying to overcome their anxiety over the irreversibility of vasectomy, there is the danger that the promise that not all possibility of fatherhood is lost with a vasectomy will be used to take advantage of human basic emotions. If an individual concerned about his future fertility feels that he must bank his sperm, then perhaps he should reexamine his reasons for a vasectomy rather than rush into it and rely on the semen bank as an escape clause. Artificial insemination with frozen semen is not always successful and a man is deluding himself if he believes that he can deposit his semen, have it frozen, and then return a few years later and be certain of having children. It is therefore essential that all men (and their wives) be fully informed of the scientific knowledge regarding human-semen cryobanking as well as the procedures and possible consequences of vasectomy. Such information should include the caution that there is no "guarantee" that semen specimens will be usable at a later date.

The Physician-Researcher and Ethical Research

Many semen banks are using stored semen to conduct fertility research. This use of frozen semen raises an immediate ethical question regarding the possible conflict of interest of a physician involved in fertility research who, at the same time, counsels his patients on the therapeutic or contraceptive benefits of banking semen. Ethical medical research requires a balancing of two important values. As counselor, the physician should value highly humane therapeutic treatment. As a research scientist, he values increased scientific success through scientific inquiry. While very often these two values are satisfactorily balanced, sometimes emphasis on one value may preclude the achievement of the other. For example, an overly ambitious investigator may, in promoting his research as well as his own scientific recognition, perform his physician/researcher responsibilities without proper regard for his patient/subject.

The urgency of this problem is clearly underscored by the warning that the promise of fertility insurance through the storage of semen may persuade some immature or poorly motivated individuals to undergo vasectomy. It may be necessary, therefore, to implement screening programs for vasectomy applicants, since preexisting instability may be a contraindication to the operation. It is imperative, however, that those seeking to store their semen in a frozen-semen bank, for whatever purpose, be informed of the research for which their semen will be used and the possible consequences. It should be made clear that their semen will be used for no other research purposes without their written consent. The importance of this becomes evident when we examine the storage agreements of the three major commercial semen cryobanks. All three banks provide for the termination of their storage agreements either upon the death of the donor or the failure of the donor or his designated representative to maintain storage payments. Unless the donor has requested that his semen be destroyed upon his death, his semen may be "destroyed," used "in advancement of medical science," or "in any other practicable manner," or for any purpose that the bank "deems fit." Except for the explicit destruction of the semen, the uses cited above are all open to a wide latitude of interpretation, with the result that the donor is more likely to be confused than "informed."

While it may be relatively "harmless" as well as agreeable to the donor for his semen to be used in research pertaining to the motility of spermatozoa, it is quite a different matter if his semen, in the name of scientific research and without his prior consent, is used to cause pregnancy by means of artificial insemination in a woman other than his wife. Yet, only one of the three commercial banks has a statement in its storage agreement which prohibits explicitly the use of any specimen "without the client's written consent, for the purpose of causing pregnancy be means of artificial insemination." Furthermore, at least one bank has suggested that semen might be used for research relating to *in vitro* fertilization, the fertilization outside the body of the female of human egg by human sperm. It is doubtful that many of those persons who contemplate banking their sperm are aware of this possibility; present storage agreements and consent forms do little to increase their awareness. It is imperative to raise the question here, however, of the ethical propriety of using donor semen without properly executed informed consent for experimentation relating to *in vitro* fertilization.

From these concerns emerge additional policy questions: What provisions should be made regarding the disposal of a man's semen upon his death or his failure to maintain storage payments? Should his semen become the property of the semen bank? His wife? His heirs? What interest does the community have in the ultimate disposal of his semen? And finally, are existing medical ethical practices and government research guidelines[5] adequate mechanisms for balancing the therapeutic and contraceptive needs of the individual with the objectives of promoting scientific research and protecting the individual as a research subject?

Genetic Applications

A couple in which both partners carry complementary genes could prevent the birth of a potentially afflicted child (with respect to the disease traits that they carry) by substituting the husband's semen with that of a donor known to be free of such recessive genes. Similar use of a donor's semen would be especially indicated in the case of a husband who is thought or known to be a carrier of a dominant gene, whereby each potential child would have a 50 percent chance of being affected.

An increase in the commercialization of human-semen cryobanking may lead to a search for the "best" donors. We know, for example, that semen specimens from different donors vary considerably in their ability to withstand the process of freezing, storing, and thawing. Thus, those donors whose semen exhibits a greater degree of freezability will father a greater proportion of progeny than would be expected with respect to their normal history of fertility. This type of discrepancy in fertility will decidedly bias the number of offspring attributable to selected donors. And, indeed, there are reports in the literature of five donors being "responsible for 90 pregnancies, one donor siring 35, and another 22."[6] This disproportionate use of donors will increase the coefficient of inbreeding which could result in an increased incidence of recessive genetic diseases. For example, a first cousin marriage brings together 1/8 of the total recessive genes carried by both individuals. Studies have demonstrated that the progeny of such marriages experience a higher-than-normal mortality and malformation rate. Furthermore, unless such frequently-used donors are thoroughly examined with respect to their genetic constitution, there exists the possibility that harmful recessive genes could inadvertently proliferate throughout the population. Thus, future generations might experience increased doses of harmful genes, such as those of sickle cell anemia and tay-sachs.

Disproportionate use of certain donors would also result in an eventual reduction of genetic variability in the population. The genetic diversity of the human gene pool has long been recognized as necessary for ensuring adaptability to future environments, so essential to survival in the face of constant evolutionary change. It would appear to be morally and biologically unwise, therefore, to tamper with the gene pool without a greater certainty of the demands and needs of future environments.

Donor Compensation

The compensation of donors raises both ethical and biological problems. Those semen banks which store donor semen rely primarily on paid donors. With an increase in commercial frozen-semen banks, the country may witness an increasing commercialization of semen-donor relationships. This tendency toward commercialization raises several questions regarding the long-term impact on social values. If semen is treated in practice as a commodity to be bought and sold, what will be the impact on prospective donors of blood, eyes, or kidneys? Will they also become just other "commodities" in the market place? And will this eventually lead to the day when a "semen market" promises "eugenically desirable semen" to the highest bidder? Furthermore, how will the entrance of semen banking into the marketplace affect the sense of obligation incurred by donors? Will remuneration be viewed as a sign that they no longer need to be concerned with the consequences of their act?

There are potentially more immediate concerns for medical practice which result from the use of paid semen donors. For example, how likely is it that a donor with a drug habit, using drugs that may cause permanent chromosomal damage, will seek remuneration for his semen as a way of maintaining his habit? Syphilis and gonorrhea are infectious diseases which can be deleterious to both the recipient and fetus. As the commercialization of semen donations increases is it likely that those who have contracted either syphilis or gonorrhea will constitute a significant proportion of paid semen donors? While a history of gonorrhea or syphilis is sufficient grounds for the rejection of a donor, there is always the dreaded and not entirely unrealistic possibility that a person who sells his semen to supplement his income not only is more likely to have such a history, but might well be willing to suppress it. Although today's semen banks rely primarily on medical students for donors, it is questionable whether this group will continue, under the pressures of commercialization, to be a readily available and desirable source in the future.

As efforts to develop appropriate public policy gain momentum, it will be useful to consider alternative or complementary programs to one which relies so heavily upon paid donors. To what extent can and should a program of voluntary donors become an integral part of human-semen cryobanking? What factors might tend to inhibit the free flow of donors? There will certainly be legal and moral questions involved in the assessment of any such program. One alternative would be to institute semen donor credits, whereby a person (perhaps a friend or relative) is able to donate his semen so that another person may receive credit for a "free" specimen (the "free" specimen would not necessarily be that of the friend or relative since this would raise its own psychological and genetic problems). No matter which alternative or complementary program is instituted, it is unlikely that society will be able to do without paid donors. An all-volunteer system would produce surpluses of some types of semen and shortages of others. To obtain sufficient quantities of semen at the required times, in the necessary places and with the desired qualities will require some system of donor compensation.

Current Public Policy and Future Outlook

Human-semen cryobanking has yet to come under the serious purview of any public policy-making body. The operation and promotion of semen banks are, with some minor exceptions, determined entirely by the persons operating them. There is some proposed or existing policy, however, which may be applicable. For example, the State Assembly of New York is considering a bill "to amend the public health law, in relation to the ownership and operation of semen banks." The proposed statute would be the first of its kind in this country and would give the Commissioner of Public Health power to adopt rules relating to the qualifications of semen-bank personnel, acceptance requirements for semen donors and the content of the advertisements and promotional materials published or distributed by semen banks. Though laudable with regard to its intent, the bill is plagued by ambiguous and misleading language (the bill has been withdrawn from the 1974 legislative calendar and will be reintroduced in 1975).

In some states, the regulation of semen banks may be accomplished through rules governing the "minimum standards for clinical laboratories." There are, however, both procedural and substantive problems with applying these standards to human-semen banks. Procedurally, semen banks are not always automatically covered by such regulations. In at least one case, a state and the director of the semen bank "arbitrarily decided that they [the bank] would work under regulations of a clinical laboratory." We must seriously question the desirability for the public welfare of such arbitrary policy-making. In a more substantive vein, while there are usually rules pertaining to the qualifications of the immediate staff of the semen bank, there are few regulations concerning the qualifications of those providing ancillary services, such as genetic and fertility counseling. There are no guidelines pertaining to informed consent; in fact, the regulations often do not apply to the research activities of the laboratories. Since semen banking was not a primary target of the regulations when drafted, there are no standards which apply directly to the freezing and storage techniques of cryobanking.

The issues discussed here demonstrate a clear need for some type of licensing or regulatory action applicable to human-semen cryobanking. In addition to potential public health problems, there is also the danger that irresponsible entrepreneurs will assume semen-bank ownership, taking unfair advantage of childless couples. While any public action must be flexible enough to take into account new advances in medical science, it is clear that the public interest would be better served by a policy designed to promote a greater degree of public accountability on the part of human-semen banks.

Of equal importance are the institutional mechanisms for promulgating and implementing necessary public policy. At least three alternatives should be considered: (1) federal-level policy-making bodies, such as the Department of Health, Education, and Welfare or, more specifically, the Food and Drug Administration; (2) public institutions at the state level; and (3) professional associations. With the rapid increase in human-semen banks it is not too soon to begin to investigate the feasibility of these or other institutional alternatives. While the medical profession should be an active participant in the decision-making process, the profession has no special capability for selecting among competing values and policies. For example, a decision to use frozen-semen banking to support a program of "genetic improvement" portends clear biological, ethical and social consequences for a broad spectrum of society. While in the past medical acts were usually of major consequence only to the patient, with little impact for persons removed from the immediate scene of the illness, the use of semen banking to promote social as well as medical goals clearly belies the credibility of such traditional thinking. Establishing appropriate public policy for these broad social questions, therefore, is the responsibility of the larger community, with the medical profession being one of many interested parties.

The benefits to be gained from semen-bank technology are potentially enormous. Yet, its application, particularly on a commercial basis, may also produce unanticipated and unwanted consequences. Heretofore, many of these issues have hardly been noted, let alone seriously considered. However, the sudden and rapid emergence of commercial semen banks is affecting an increasing number of lives daily and it is not too soon to begin to assess the many policy questions which are surfacing.

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Stress:
A Report from Blue Cross of Connecticut

Free copies of the *Stress* report may be obtained from the Public Relations Department, Connecticut Blue Cross, 370 Bassett Road, North Haven, CT. 06473.

Blue Cross describes the report as having been prepared not for the physician, the psychologist, or other professional in the field of stress but for the layman—the working man or woman, the housewife, the high school or college student, the retired man or woman and others who want to learn more about a subject that seems more and more to affect the general health and happiness.

The articles cover an overview of the whole subject of stress, followed by chapters on infancy and childhood, adolescence and aging. The next four cover stress in the home, on the job, in the environment, and stress caused by changes—good changes, as well as bad, in our ways of living. One of the chapters describes what is commonly called the "nervous breakdown," followed by a special article on learning how to relax.

Some quotes: "One social theory of aging, called 'activity theory,' says that the person who ages successfully is the one who stays active . . . In contrast to this, the 'disengagement theory' of aging has been proposed . . . By doing only essential things and by eliminating nonessential ones, the individual can deal with the loss of energy and role that age brings."

"The biggest stress for all of us these days, no matter what our profession, is money."

(Continued from page 6)

The court thought the argument "frivolous." "To accept plaintiffs' argument," the court asserted, "would be to invalidate all rules of general application adopted by the supreme court regulating the professional conduct of attorneys and their relationship to their clients and to the courts." The court believed that the power of the court to make reasonable rules and regulations regarding the conduct of attorneys is "not open to question," and that the power so vested in the supreme court to regulate the practice of law included the power to adopt a reasonable rule establishing the outer limits of permissible contingent fees in tort litigation.

Leaving for consideration at a later date the question of the reasonableness of the percentages set out in the rule, the court expressed its satisfaction that the rule was a permissible method of exercising the court's power over fee arrangements between attorneys and their clients by a rule of general application which provided advance notice to the bar of the maximum fee the court deemed fair under ordinary circumstances and at the same time provided protection to the client from overreaching more expeditiously than on a case-by-case review of individual fees.

(American Trial Lawyers Association v. New Jersey Supreme Court, Superior Court of New Jersey, Appellate Division, February 14, 1974, Kolovsky, J., 316 A. 2d 19.)

An Artificial Pancreas

A system for the automatic continuous control of sugar in the blood of diabetic patients that simulates the performance of the normal pancreas has been developed by Miles Laboratories. The first commercially available unit was sold to the University Medical Center in Ulm, West Germany, where it has been successfully used since June to manage several severely ill diabetics.

The system consists of an analyzer for the continuous micro-measurement of blood sugar, a microcomputer for precise calculation of the insulin or glucose required to maintain the patient's blood sugar level within the normal range and a delivery system for infusion in exact dosage. It maintains normal levels of blood sugar in the diabetic patient regardless of diet or stress—a level of physiological control that is rarely if ever achieved by conventional diet and insulin therapy.

This insulin delivery system will have important applications in diabetes research, training and treatment centers, especially in the management of insulin-sensitive diabetics and diabetics in coma, undergoing surgery or kidney dialysis or who are pregnant. The system is also a step toward the development of an artificial pancreas that diabetics can wear on their persons.

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Indications: Pro-Banthīne is effective as adjunctive therapy in the treatment of peptic ulcer. Dosage must be adjusted to the individual.

Contraindications: Glaucoma, obstructive disease of the gastrointestinal tract, obstructive uropathy, intestinal atony, toxic megacolon, hiatal hernia associated with reflux esophagitis, or unstable cardiovascular adjustment in acute hemorrhage.

Warnings: Patients with severe cardiac disease should be given this medication with caution. Fever and possibly heat stroke may occur due to anhidrosis.

Overdosage may cause a curare-like action, with loss of voluntary muscle control. For such patients prompt and continuing artificial respiration should be applied until the drug effect has been exhausted. Diarrhea in an ileostomy patient may indicate obstruction, and this possibility should be considered before administering Pro-Banthīne.

Precautions: Since varying degrees of urinary hesitancy may be evidenced by elderly males with prostatic hypertrophy, such patients should be advised to micturate at the time of taking the medication.

Overdosage should be avoided in patients severely ill with ulcerative colitis.

Adverse Reactions: Varying degrees of drying of salivary secretions may occur as well as mydriasis and blurred vision. In addition the following adverse reactions have been reported: nervousness, drowsiness, dizziness, insomnia, headache, loss of the sense of taste, nausea, vomiting, constipation, impotence and allergic dermatitis.

Dosage and Administration: The recommended daily dosage for adult oral therapy is one 15-mg. tablet with meals and two at bedtime. Subsequent adjustment to the patient's requirements and tolerance must be made.

How Supplied: Pro-Banthīne is supplied as tablets of 15 and 7.5 mg., as prolonged-acting tablets of 30 mg. and, for parenteral use, as serum-type vials of 30 mg.

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Modern Age Cannibalism: Organ Transplants Via the Oral Route?

Hans H. Neumann, M.D.

The widely-held notion that cannibalism among civilized people is unthinkable turns out, upon investigation, to be false. Unpalatable as the thought may be, a review of recent history reveals sufficient medically recorded evidence to show that cannibalism, even among people of advanced cultures, is not at all exceptional. The now-famous Andes experience of 1972 is only the most recent of a number of similar incidents; and as far back as the middle of the last century, documentation can be found of cannibalism among our own forebears in the United States. How one views such incidents depends upon the balance between one's scientific and religious orientations, as well as on one's ability to identify with those who are driven by circumstances to eat human bodies. Some may view cannibalism under critical conditions to be no different than organ transplants via the oral route.

This view was, in fact, expressed by a medical student who was one of the survivors of the plane that crashed two years ago in the Andes. Sixteen survivors managed to stay alive on those icy mountain peaks for 71 days by eating all that was edible of the bodies of the other 23 persons who had perished in the disaster. (A book describing the Andes ordeal, *"Alive"* by Piers Paul Read, can be highly recommended to physicians for its fascinating, day-by-day account of human actions, reactions and endurance under extreme stress.) In another incident in 1973 in the Canadian Arctic, a pilot on a medical mercy mission was stranded 31 days and was able to survive his ordeal by eating the flesh of the nurse who had accompanied him.

Some may be put off from reading about such incidents because they fear the accounts will be full of horrifying details. Strangely enough, the reader of such tales soon becomes inclined to accept these events matter-of-factly as the anticipated emotional reaction is supplanted by a combination of awe for the length of survival, and by the apparent singularity of the situations.

In the medically recorded evidence of cannibalism in modern history, conditions have rarely been as propitious as those which provoked the two recent incidents in the Andes and the Arctic. In both of these cases, the starving survivors were in climates where ice and snow acted as health safeguards in preserving the dead bodies of the victims.

In present-day America, where the concern of a large part of the population is to resist the seductive lure of food and the temptation to overeat, there are few acts as revolting as eating one's fellow man. But in times of severe famine and during periods of prolonged starvation—and this applies even to Western societies and to modern times—traditions and taboos have had a tendency to melt away. As more areas of the globe are faced with food shortages and the threat of starvation, and as the highly developed nations become increasingly unable to fill the food gap of others, who knows what developments we may see in terms of facing or even accepting human consumption by other humans? Repulsive as this thought may be, it's worth looking at what happened when, on other occasions, civilized people were faced by death through starvation.

One of the major famines of this century affected Russia in the years between 1918 and 1922 and numerous, detailed reports by reliable observers, some of them still alive, document the terrors of that period. America sent a relief team and contributed sixty million dollars to try and lessen the horrors of mass starvation. An American physician, H. H. Fisher, described in an historic document the work and findings of this relief mission. In it he states, "To the peasants crazed with hunger, who had come to eating the flesh of animals dug up from the ground, the practice of eating human flesh was not such a long step. In some instances, cannibalism was preceded by murder, with the meat being sold for public consumption." He records an incident in the city of Orenburg where an investigation "discovered that the murderer had cut up the body of his victim and sold the flesh in the bazaar."

Fisher's report also quotes the work of a pathologist, a Dr. Frank of Kharkov University who investigated a number of cases of cannibalism. "He was able to establish the authenticity of twenty-six cases in which humans were killed and eaten by their murderers. He found seven cases in which murder was committed and the bodies sold for food. In these latter, the flesh was disguised in sausage form and placed on the open market." These incidents resulted in the issuance of an order by the Public Health authorities forbidding the sale of meatballs and "all forms of hashed meats."

Yet, despite the fact that during the extreme hunger years, 1921-22, when the Russian District of Samara alone accounted for hundreds of thousands

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DR. HANS H. NEUMANN, Director, Preventive Medicine, Department of Health, New Haven, Conn.

of hunger deaths, existing records show that there were only a few hundred cases of cannibalism and that the instances of murder for the purpose of cannibalism could be counted in terms of dozens. The resort to human flesh, after months of starvation, appeared to be an animal-like reaction without painful emotional overtones.

There are also records of the cannibalistic effects of semi-starvation in German concentration camps in 1945. When the British Army took over the camp at Belsen in the second half of that year, Dr. F. M. Lipscomb, a psychiatrist in the British Army described the mental state of the inmates. "Emotional response," he wrote, "had become progressively lowered and consciousness of sex was lost. Eventually, all self-respect disappeared and the only interest left was to obtain something which could be eaten, even human flesh. There was a blunting of sensitivity to scenes of cruelty and death."

A vivid description of a scene in a German prisoner of war camp during World War II is given by another physician, Dr. B. Markowski, in a 1945 issue of the British Medical Journal. "The dinner was composed of a watery vegetable soup," wrote Dr. Markowski, "doled out once a day in meager quantities. It was winter, I saw a long line of terribly emaciated Russian prisoners in rags. Their feet, blue with cold, were sometimes bare, and sometimes they wore wooden clogs. They held their mess-tins in trembling hands, but it was their eyes that drew my attention. They had nothing human in them; they were deeply set, shining, and fixed with an animal expression. They seemed not to notice that some of their comrades had fallen from exhaustion and that they were treading upon them, doing them to death by the trampling of their clogs." Following this description, one is no longer surprised to read that there was definite evidence of cannibalism in this camp, and that pieces of flesh had been cut out of the dead bodies and eaten by the survivors.

There is an historically famous incident of cannibalism in our own country, and not so long ago. It took place among a group of marooned American settlers, the Donner Party, whose exploits and tragedies have often been described but quickly put out of mind.

In 1846, a group of families from Illinois, under the leadership of a farmer named Donner, decided to settle in California. While traveling through the Sierra Nevada mountains, they were overtaken by the snows, and of the 81 persons in the party, 45 died of starvation and exhaustion. Existing records and diaries provide a good account of behavioral changes that can take place in an American community under conditions of prolonged starvation. At first, the inadequate food supplies consisted of meat from the cattle the Donner Party had brought along. Later on, pieces of beef hide were cut into strips, boiled to the consistency of glue and swallowed, albeit with great effort. The cattle were lost in the onslaught of the blizzards and after weeks on very low rations "the little field mice that crept into the camp were caught and used to ease the pangs of hunger and even the barks and twigs of pine were chewed."

But extreme hunger soon led to a change in the group's moral principles. The first of the expeditions sent out for help reached a settlement only after having eaten the flesh of their comrades who died on the way. Another group was trapped by a new storm and became known as the "Starved Camp." In a development independent from that of the first group, the eleven people in this camp turned to the unburied dead for food in order to save those who were still alive.

The diary of one of the members of the Donner Party, known only as Mr. Breen, was published in 1910. Here is an entry for February 26, 1847: "Hungry times in camp . . . Mrs. Murphy said here yesterday that she thought she would commence on Milt and eat him. I don't know that she has done so yet, it is distressing." When a relief party finally reached this camp, only one adult was found to be still alive. He had sustained life by cannibalism and was suspected of having murdered the last remaining women.

As with the more recent tragedies in the Andes and in the Canadian Arctic, the Donner Party's biggest impact on outsiders was not so much the remarkable feat of the length of their survival, but of their recourse to cannibalism. One who has not experienced a month of total starvation is hard put to imagine what it is like, and not really qualified to pass moral judgment. In the cases recorded in the Western hemisphere, hunger had persisted for many weeks and the bodies of the dead were also preserved by the cold.

Nowadays, the surgical transplantation of organs from the living or dead is morally accepted without question. Still to be bridged is the not-so-subtle physiological difference between the parenteral surgical and the oral route for organ transplants—aside from the uncompassioned term of "cannibalism" ("anthropophagy" sounds less emotional and damnatory). Yet the cause of cannibalism may have been advanced by the previously mentioned argument of one of the marooned medical students in the Andes when he justified his actions as being analagous to organ transplants in which the bodies of the recently deceased are permitted to be used in order to save the endangered lives of others.

Support of Biomedical Research—1974

In 1967 the American Medical Association's recognition and support of the national biomedical research effort were expressed when the House of Delegates accepted the *Report of the Commission on Research* and adopted the recommendations contained therein. Of the Report's fifteen recommendations dealing with various aspects of biomedical research and education, the first two, and the most important, were as follows:

1. "The American Medical Association should support in general the Federal biomedical research program." This sentence was qualified by the proviso that the Association should assume obligation for a continuing critical discussion and analysis of the program."
2. "The Programs of the National Institutes of Health should be recognized for their contributions to the national biomedical research effort."

In adopting in 1967 the recommendations of its Commission on Research, the American Medical Association took an affirmative view of federally funded research in medicine and biology. The condition of biomedical research in the United States in 1974 is warrant for the Association once again to declare itself on this subject. Only a decade ago biomedical research was one of the nation's most vigorous and splendid scientific endeavors. Now it is seriously faltering, having been victimized by inadequate federal funding, by budgetary imbalances dictated by expediency, by restricted and uncertain programs for training researchers, and by an increasing political presence among administrators of, and advisors to, the National Institutes of Health. To reverse these trends, a mere allocation of more monies to research in general will not suffice. Rather, corrective measures will entail specific and dedicated efforts to shore up each of the several levels of biomedical research. These include research that has as its objective the acquisition of basic knowledge, whether or not it bears any known relation to a disease, clinical investigation that may be either fundamental or applied, and, when conditions are appropriate, targeted research. An adequate pool of manpower to carry out the necessary tasks must also be assured.

Because of its conviction that biomedical research is one of the cornerstones on which good health care rests, the American Medical Association wishes to endorse and promote the following principles.

1. The support of biomedical research is the responsibility of both government and private resources. The federal government, for its part, must sustain, with high priority, major appropriations to all federal agencies that have responsibility for the support of biomedical research, including training for this research. Such support is warranted not only for humanitarian but also for economic reasons. The cost benefits of medical research are dramatically illustrated by the investments made in virus research that led to several effective vaccines against infectious disease. At today's hospital costs, for example, the nation saves $2 billion per year because of the vaccine against poliomyelitis. Equally large savings have resulted from chemotherapy for tuberculosis. Indeed, it has been suggested that one dollar invested in research saves many dollars in subsequent medical care costs.

Inflation and increasingly sophisticated technology have increased medical research costs dramatically. It is inappropriate to compare today's research expenditures with those of an earlier period in absolute dollar amounts. Government appropriations and authorizations for biomedical research and training must take these factors into account; at a minimum, support for research and training should be established and sustained at a level that will bear some consistent relation to the nation's total expenditure for health.

2. The National Institutes of Health must be budgeted so that they can exert effective administrative and scientific leadership in the biomedical research enterprise. It is important that enabling legislation ensure the economic independence of the Institutes. The prerogatives and non-political nature of the NIH director, the Institutes' directors, and the advisory bodies must also be protected. Strengthening the independence of the Institutes, however, does not preclude changes in the overall NIH structure, or that of the component Institutes, which must be flexible and accommodate to new needs.

Funds appropriated and released for the direct support of extra-aand intramural research must be adequate and reasonably assured from one budget year to the next.

3. An appropriate balance must be struck between support of project grants and of contracts. Significant, basic discoveries will continue to evolve from independent, investigator-initiated research, the type of imaginative discoveries that ultimately led, for example, to the development of poliomyelitis vaccine and of streptomycin for treating tubercu-

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Report of the Board of Trustees of the AMA to the House of Delegates, AMA Clinical Convention, Portland, Oregon, Dec. 1974.

losis. Thus a majority of the money designated by Congress for research should be awarded by the grant mechanism, ranging from broad institutional to individual project grants.

On the other hand, the contract mechanism is entirely appropriate for a number of objectives, particularly when a discovery is to be exploited and developed. Moreover, studies in the public interest may justifiably be designed and proposed by granting agencies. The contract mechanism should, however, attempt to make use of external peer review to the greatest extent feasible.

4. Federal appropriations to promote research in specifically designated disease categories should be limited and made cautiously. Concentrating research funds in one disease area, such as cancer, may not be beneficial either to the total biomedical research effort or even to cancer research itself.

5. Funds should be specifically appropriated to train personnel in biomedical research. Without adequate numbers of personnel trained in both basic and applied biomedical research, new discoveries for the prevention and care of disease will be unlikely. Indentured service, or financial or other penalties that encumber the use of research training funds by either institutional or individual awardees, are undesirable.

6. Grants should be awarded under the peer review system that has functioned so effectively for over two decades. The study sections composed of peers that evaluate scientific merit and the judgments of councils on relevance and priority have proven to be sound. Until a more effective or more fair system is devised, no shortcuts should be made in the present system under the pretext of economy.

7. The roles of the private sector and of government in supporting biomedical research are complementary. More vigorous and more venturesome investments in biomedical research by industry and foundations is indicated to balance the necessarily routinized and bureaucratic contributions of government. Conversely, government should encourage and facilitate research support by the private sector. Changes in the tax laws that might jeopardize research funds in the private sector should be opposed. In addition, mechanisms should be developed to integrate the programs underwritten by public and private funds to prevent waste and unnecessary duplication of effort. Such integration should, however, be entirely voluntary and not obligatory.

8. Although the AMA supports the principle of committed federal support of biomedical research, the Association will not necessarily endorse all specific legislative and regulatory action that affects biomedical research. The Association will study legislative proposals closely, weigh priorities, examine past and current developments, and will be prepared to offer suggestions for improvement, or even to oppose what appears as unwarranted or disadvantageous.

9. To implement the objectives of section 8, the Board of Trustees will establish mechanisms for continuing study, review and evaluation of all aspects of federal support of biomedical research.

10. The American Medical Association will accept responsibility for informing the public on the relevance of basic and clinical research to the delivery of quality medical care. It is important that the public be familiar with the goals and methods of biomedical science so that the people and their representatives can effect sound scientific policy.

ADDENDUM

Summary of Recommendations of the Report of the Commission on Research (1967)

1. The American Medical Association should support in general the Federal biomedical research program. However, because in the public mind research tends to become enshrouded in such an aura of divinity as to exclude critical discussion and analysis of all that is advanced in its name, the AMA has an obligation to the public and to the medical profession to question any facet of the Federal biomedical research program which it may believe to be ill-advised or which it believes to be in need of constructive counsel.

2. The programs of the National Institutes of Health should be recognized for their contributions to the national biomedical research effort.

3. The Council on Medical Education of the AMA, in cooperation with other interested organizations, should be asked to make additional and progressive studies on the effects of research grants on teaching in medical schools. It should seek and recommend means for providing enhanced status and rewards for excellence in teaching.

4. The AMA should support responsible action designed to make available to selected schools of good potential, which have not developed adequate research establishments, special "development" funds to initiate or enlarge their research programs. These grants should also foster better geographical distribution of "centers of research excellence" among medical schools and universities.

5. The AMA should urge that the purpose of grants be identified precisely so that the Congress

and the nation may know, with reasonable certainty, what is being supported, as a basis for future decision making.

6. To strengthen the review mechanism, membership on NIH study sections should provide for a sufficient rotation to ensure continuous infusion of new blood and to prevent the development of a monolithic, elite, decision-making "establishment." The same principles of rotation should apply to the Advisory Councils of the NIH. While due attention should be given to such factors as geographic distribution, the main consideration in appointing members to the Advisory Councils should be professional attainment and eminence of judgment.

7. A new statutory mechanism of overall review and counsel, in an advisory relationship to the director of the National Institutes of Health, should be established in order to assist in overall program planning and to provide additional checks and balances on program decisions. Membership on this advisory group should consist of men and women of demonstrated professional eminence and judgment. We believe the advisory body should have independent status, under law, to assure that its recommendations and actions will have their intended impact regardless of changes in administrative leadership.

8. Accountability for disbursement of public funds should be maintained, but this accountability should depend primarily on strengthening of administrative capabilities of educational institutions.

9. The AMA should urge and support legislation providing for Federal reimbursement of all allocable institutional costs of research projects authorized and funded by the Federal Government.

10. The AMA should urge and support legislative and administrative action designed to shift more decision-making responsibility for biomedical research from NIH to participating research institutions. To this end, increased use of the "institutional grant" and of the "program grant" should be actively supported. Developments relating to, or affecting, the mix of institutional, program and project grants to academic institutions should be carefully and continuously studied and analyzed for future guidance.

11. The AMA, in cooperation with other interested organizations, should conduct workshops and seminars of academic and medical school leaders and of those Federal administrators who grant and administer federal research funds, to review mutual responsibilities and relationships, to conduct discussions of developing problems, and to develop new techniques for the better use and management of the vast Federal funds now being made available.

12. Because of the rapid changes which are occurring in the organization of medical practice and the financing of health care, research in the delivery of health care is of great importance and should be encouraged, provided it is conducted under proper auspices in accordance with sound research design and methodology.

13. The imbalance between biomedical research and education, caused by the heavy, but desirable, Federal support of research, should be corrected by supporting measures that will materially increase both private and public funds for the support of the educational programs of the medical schools. First, among these measures, a more liberal income tax treatment should be allowed to the donors of private funds for medical education, to create increased incentives for them to contribute to medical education. Second, there should be allotted a greatly increased amount for operational expenses of medical schools, to be matched by those schools through private or local governmental sources. Every effort should be made to keep the Federal contribution on a supplemental basis, and the AMA should not support legislation that fails to do so.

14. The basic principles presented by the pharmaceutical industry on June 1, 1965, before the Subcommittee on Patents of the Senate Judiciary Committee should be endorsed, namely:

(a) Provision should be made, in substantially every case, for the grant or license of exclusive rights in a scientific medical discovery to some industrial concern to assure that drug inventions, even if resulting in some part from Government-financed research, are really developed and made commercially available to the people.

(b) When Government funds have solely or primarily developed the invention, it is equitable and rational for the Government to hold the proprietary rights to the invention and to receive reasonable royalties from a licensee, or from licensees, who will manufacture and commercially market the invention.

(c) Where Government funds did not solely or primarily produce discovery and development of the invention, the cooperating contractor-developer alone should have the proprietary rights in the invention.

15. The Board of Trustees should provide for a continuing watch and review of developments in the areas studied by its Commission on Research.

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Legal Aspects of Cardiac Pacemakers

Elliot L. Sagall, M.D.

Introduction to Pacemakers

Under normal conditions, each human heart beat is triggered by an electrical impulse that is generated spontaneously within a specialized small piece of tissue located in the wall of the right atrial heart chamber. This natural heart pacer, termed the sinoatrial node (S-A node), fires rhythmically in response to bodily needs at an average rate of about 70 beats per minute resulting in approximately 100,000 heart beats per day. The rate of firing slows or quickens based upon signals sent to the pacer via the nervous system and in response to minute changes in the chemical composition of the arterial blood which brings this tissue its oxygen and other nourishment.

The electrical impulse originating within the S-A node travels rapidly through the musculature of both right and left atrial chambers causing them to contract and propel the blood contained therein into the ventricular chambers of the heart.

The stimulating electrical charges, now having traversed the atrial musculature, gather within specialized tissue, called the atrioventricular node (A-V node), located in the upper portion of the septum which separates the two ventricular chambers. These impulses are then transmitted to the ventricular musculature via the specialized conducting tissues of the bundle branch system (the Bundle of His, and the right and left bundle branches) and then through the so-called Purkinje fibers into the musculature of the ventricular walls stimulating them to contract in proper sequence after atrial contraction to effect an orderly emptying of blood from the heart.

Nature's design of the heart's conduction system enables a rhythmical, regular contraction of the heart muscle so that blood contained within the heart cavities is pumped from atrial to ventricular chambers, then into the pulmonary and arterial circulations to bring oxygen and chemical nourishment to all the cells and tissues of the body.

Similar to any electrically operated device, the natural heart pacemaker and its conduction system are subject to breakdowns and circuitry failures. Improper functioning of the impulse generator or breaks, blockage, delays of short circuits in the conduction system tissues due to congenital defects, acquired disease or trauma may lead to physical incapacity, invalidism or death. Stoppage of the sinus node impulse formation or partial or complete blockage of the transmission of the S-A node impulse through the conduction system to the ventricles may lead to fainting or to death from the sudden standstill of the ventricles (Stokes-Adams attacks) or may produce a very slow heart rate (30 to 40 beats per minute or less) which prevents proper oxygenation and nourishment of body tissues and may lead to symptoms of excessive weakness, dizziness, feelings of faintness and actual faint with periodic loss of consciousness.

It is in the treatment of diseases of the natural heart pacemaker and of the conduction system, particularly complete atrio-ventricular heart block, that the artificial cardiac pacemaker has proved most beneficial. By means of this device—a battery-powered unit delivering stimulating electrical impulses to the heart muscles via fine wires implanted into the muscular wall (myocardium) or securely positioned against the lining of the ventricular cavity (endocardium)—many invalided cardiac patients have been restored to almost normal activity and relieved from the previously, ever-present imminent threat of unpredictable fatal cardiac arrest which haunts patients suffering from complete A-V heart block.

Scattered references to the use of electric currents in reviving arrested hearts and in the regulation of heart action have appeared in the medical literature since the turn of the 19th century. The modern era of artificial pacemaker development and clinical application of such devices, however, derives mainly from the report of Dr. Paul Zoll in 1952 of the successful sustained resuscitation of the human heart in a patient with prolonged ventricular standstill by means of electrical currents repetitively administered through the intact chest wall. The effectiveness of external pacing by this means established the feasibility of artificially maintaining the human heart beat in many situations where effective heart contractions could not be spontaneously maintained.

Demonstration by Dr. Zoll and other investigators of the success of external pacing devices in patients with Stokes-Adams disease prompted increased scientific interest in this means of treatment and ultimate development of permanently implantable pacemaker units which free the patient from reliance on external machines and allow more normal activity.

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The first successful human implantation of an internally powered pacemaker was performed by Chardack and co-workers in 1960. Subsequently, rapid technical developments and continued improvement and sophistication of pacemaker devices has led to expanding clinical application so that this therapeutic modality has now achieved widespread acceptance in the armamentarium of the cardiologist and has been proved on many occasions to be not only lifesaving but also able to restore many previously crippled cardiacs to useful activities.

Estimates point to permanently implanted pacemakers now in about 100,000 persons in the United States, and the rapidly expanding rate of pacemaker implantation (over 10,000) per year promises perhaps 150,000 pacemaker patients by 1975.

As with the performance of any medical or surgical procedure or treatment, the implantation of a cardiac pacemaker has potential legal implications. Pacemaker therapy itself, however, by reason of its nature involves certain medical problems which, in turn, create additional issues of potential legal concern.

Areas of Potential Legal Liability

Potential legal actions in tort based upon charges of malpractice may arise against treating and consulting physicians, surgeons who implant pacemaker devices, hospitals and manufacturers should a patient suffer ill-effects attributable to negligence in (1) reaching a decision whether to implant a pacemaker when such is clearly medically indicated; (2) negligent failure to warn of potential complications, after-effects, risks and hazards; (3) improper selection of the type of device and pacemaker system appropriate to the patient's problem; (4) negligent post-implantation follow-up care and advice; and (5) improper design or manufacture of the pacemaker instrument and its impulse generator.

Additionally, primary treating or consulting physicians may be subject to courtroom indictment for "technical battery" on grounds of lack of "informed consent" in cases where complications occur and there is demonstrated a failure to have warned or to have advised the patient properly and adequately of the "substantial" risks of the procedure.

In still another area of the law, physicians may become legally liable for damages for "breach of contract" should there be evidence of a guarantee, implied or otherwise made, of achievement of a specific result or "cure" which is not accomplished.

Under products liability laws, manufacturers of a defective cardiac pacemaker may be held legally responsible for harmful consequences of pacemaker failures under several avenues of legal action.

Recovery for pacemaker failure may be obtained on the basis of negligence of a defendant manufacturer in departure from standards of due care with respect to the design, manufacture, assembly, packaging, inspection for defects, or testing of the instrument for proper function. (Courtroom proof of this contention, however, as a practical matter, is usually quite difficult.)

Legal action against a manufacturer may also be based upon alleged breach of warranty with claim of injury as a proximate result of the nonconformance of the product with manufacturer's assertions of warranties. In such type of action, there is no need to prove negligence in order to recover. The plaintiff need only prove that the pacemaker when sold to him was defective, that because of the defect the product did not conform to the broad requirement of "fitness and merchantability" and that he was injured as the proximate result of the defect.

Under expanding principles of strict liability in tort, responsibility for personal injury to a consumer from a manufactured product proved defective or not fit to perform the function for which it was designed shifts to the manufacturer despite his having exercised all possible due care in the design and manufacture of the instrument and the lack of evidence of negligence on his part. Current trend to increased and widespread application of the doctrine of strict product liability makes it likely that manufacturers of pacemakers as well as other medical devices will be held legally liable to harm consequential to use of a product similar to the manufacturer of commercial products.

The hospital may also be liable for damages if it can be shown to have been a vendor or an agent of the vendor and, therefore, liable under a breach of warranty theory and/or if it is demonstrated negligent for having supplied defective equipment per se or for failure to inspect for discoverable defects.

Third parties, too, may become legally liable for pacemaker catastrophes should a manufacturer or entrepreneur of restaurant and other food vending establishments using microwave ovens fail to display warning signs of potential danger to pacemaker patients.

The advent of nuclear-power pacemakers brings theoretical risk of atomic radiation injury to the wearer as well as those who come in close contact with him and thereby potential suit for damage should harm ensue.

In illustration of another source of potential legal problems was the recent newspaper announcement by the General Electric Company that in 487 patients with certain General Electric instruments the device might develop a defect leading to danger-

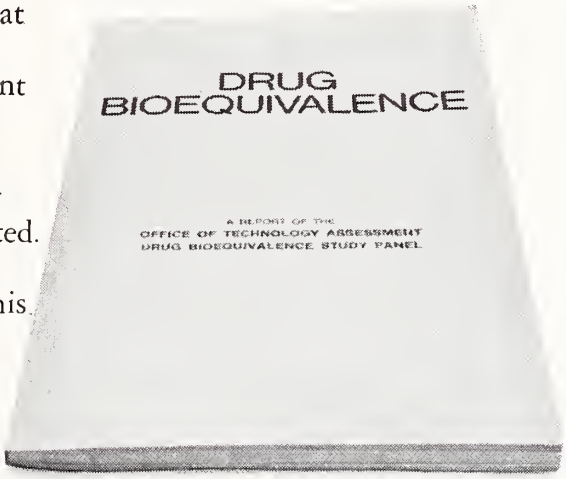
the weight of scientific opinion:

If the pharmacist substituted a chemically equivalent drug for the one you have specified for your patient—could you be certain of that product's safety and effectiveness simply because the chemical content was the same?

Definitely not, unless bioequivalence tests and other quality assurance checks had been conducted. The pharmaceutical industry and many scientists have maintained this position for years, but others have questioned it. Now the Office of Technology Assessment of the Congress of the United States has reported on the issue in its Drug Bioequivalence Study.*

Here are a few definitive statements in the O.T.A. report:

"...the problem of bioinequivalency in chemically equivalent products is a real one. Since the studies in which lack of bioequivalence was demonstrated involved marketed products that met current compendial standards, these documented instances constitute unequivocal evidence that neither the present standards for testing the finished product nor the specifications for materials, manufacturing process, and controls are adequate to ensure that ostensibly equivalent drug products are, in fact, equivalent in bioavailability.



DRUG
BIOEQUIVALENCE

A REPORT OF THE
OFFICE OF TECHNOLOGY ASSESSMENT
DRUG BIOEQUIVALENCE STUDY PANEL

"While these therapeutic failures resulting from problems of bioavailability were recognized and well documented, it is entirely possible that other therapeutic failures and/or instances of toxicity that had a similar basis have escaped attention."

The Pharmaceutical Manufacturers Association supports federal legislative amendments that would require manufacturers of duplicate prescription pharmaceutical products, subject to new drug procedures, to document:

(a) chemical equivalence; and (b) biological equivalence, where bioavailability test methods have been validated as a reliable means of assuring clinical equivalence; or (c) where such validation is not possible, therapeutic equivalence.

In addition, the PMA supports federal legislation that would require certification of all manufacturers of prescription products before they could start in business, annual inspections and certification thereafter, and strict adherence to FDA regulations on good manufacturing practices.

The overall quality of the United States drug supply is excellent. But only a total quality assurance program, envisaged in these and other policy positions adopted by the PMA Board of Directors in 1974, can bring about acceptable levels of performance by all prescription drug manufacturers and thereby assure the integrity of your prescription...

P·M·A

Pharmaceutical Manufacturers Association
1155 Fifteenth Street, N.W.
Washington, D.C. 20005

*Copies of the complete report on Drug Bioequivalence may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

protecting the integrity of your prescription

ous speed-up. The company's publicized "pacemaker recall" with offer of free replacement units and costs of surgery and hospitalization created widespread fear in large numbers of pacemaker patients even in those whose units were not of this manufacturer nor of known pending trouble.

And, in still another area of personal injury law, pacer malfunction alleged to mechanical disruption of circuitry or to breakage of wires and electrodes may become an issue in causation assessment in a patient whose pacemaker begins to show evidence of malfunctioning after an automobile accident or other trauma.

Thus, theoretically, the potential legal implications of artificial heart pacemakers are many, and more can be anticipated as the use of this therapeutic device expands. Accordingly, the practicing attorney faced with a possible pacemaker case should, as a first step, familiarize himself with the types of pacemaker instruments and systems presently available, the factors affecting the prescription of a pacemaker and the selection of the instrument and system to be used by a physician, the route of implantation to be chosen and the complications, the risks and the hazards of this type of treatment. In addition, the attorney should be familiar with currently recommended follow-up care and the recognized causes, both internal and external, of early pacemaker failure as well as the means of detecting impending pacemaker break-down and of preventing death or other serious complications in pacemaker dependent patients.

Basics of Pacemaker systems

The usual components of an artificial cardiac pacemaker consist of four or five basic units. (1) A power pack generates the electrical current which stimulates the patient's heart to contract. (2) A firing unit releases each artificial electrical stimulation dependent upon how it has been set or programmed. (3) Transmitting wires carry the pacing impulses from the pacemaker to the heart. (4) Electrodes embedded either within the heart muscle (myocardium) or firmly positioned against the lining (endocardium) of the right ventricular cavity deliver each electrical stimulation directly to the heart muscle. And (5) in so-called "demand" cardiac pacemaker, the stimulating electrode placed within the patient's heart also "senses" or receives electrical data generated by the naturally induced heart contractions and relays these back to the firing unit which is preprogrammed to fire or to withhold a scheduled firing depending upon the information brought to it.

Continuing technologic advances and expanding numbers of pacemaker manufacturers now allow considerable latitude in choice of pacemaker systems and instruments. Presently, some five or more major manufacturing concerns make two main types of pacemaker systems, four variations of pacer units and over 30 different models of pacer instruments. Generally, the units and parts are not interchangeable.

The cost of a cardiac pacemaker instrument ranges from $650 up to $2,000 depending upon the complexity of the unit. Surgical fees for implantation generally range from $500 up to $1,500. The minimal duration of hospitalization for an uncomplicated implantation is in the range of two to three days with a transvenous insertion and seven to ten days when electrodes are directly imbedded into the heart by means of open chest surgery (thoracotomy).

In emergency situations when a patient with pacing problems is not able to identify the make or type of his pacer unit, routine chest x-ray may help by revealing a particular shape or arrangement of batteries and other electronic components that often enable identification of the manufacturer. As further aid in pacer identification by x-ray one manufacturer has now adopted the policy of placing radiopaque letters between two of the batteries which readily identify the units.

Fixed-rate pacers (also called asynchronous, parasystolic or competitive pacemakers), although the earliest type of artificial pacers employed, are still the least complicated of present day instruments and, therefore, the most reliable in that they are least likely to develop component failures.

The asynchronous cardiac pacemaker is designed to fire repetitively and rhythmically at a preset, fixed rate (usually in the range of 70 beats per minute) unaffected by the electrical impulses generated by the patient's natural heart rhythm. Patients with this type of pacing system generally maintain a constant heart rate independent of demands placed upon their heart. However, when the abnormal rhythm for which the pacer was originally inserted changes or disappears, naturally induced heart beats may compete with stimulation from the artificial pacemaker. Competition of this sort rarely creates a potentially life-threatening danger due to the possible precipitation of rapid uncontrollable ventricular tachycardia or ventricular fibrillation, but because of this danger, the use of fixed-rate pacemakers usually is restricted to those patients with complete A-V heart block in whom this conduction defect is thought to be permanent and not paroxysmal.

Demand (synchronous, sensing or noncompetitive) pacers are employed primarily to pace patients with intermittent A-V heart block or other paroxysmal heart rhythms for which artificial pacemaking is clinically indicated. Demand pacemakers are programmed to trigger patient's heart to contract when the rate of natural heart contractions falls below a preset range. Within the range set, the natural heart pacer controls the rhythm and rate of the patient's heart beats thereby enabling normal response to demands placed upon his heart.

When the patient's own heart rate falls abnormally below the preset range of the pacemaker, the artificial pacing system takes over and thus protects the patient from ill-effects due to a persistently abnormal heart rate that is too slow for safety. Artificial heart pacing is then maintained until the abnormal situation corrects itself and the normal heart pacemaker can once again keep the heart beat within a safe preset range. Once this occurs the demand pacemaker stands by or fires in synchrony with the heart beat to step in once more only when necessary. Demand pacemaker units, thus, avoid the potentially dangerous competition which may occur between the patient's natural heart beat and that of a fixed artificial pacing system.

Three types of demand pacemakers are presently in common usage. The two most commonly employed are programmed to the R wave of the ventricular contractions; the third is programmed to the P wave of atrial contraction. Other possible pacemaker systems employing more sophisticated sensing and timing mechanisms are under investigation, and it is likely that instruments will soon be devised to allow artificial pacing to more closely proximate natural heart pacing.

Ventriculary-sensing pacing systems are the most commonly employed artificial pacers at the present time. These devices are programmed to the R wave of the natural heart contraction. One system is devised so that the artificial pacemaker will fire at a preset rate unless the unit receives a message that the patient's heart itself has contracted. This type of device is known as a ventricular-inhibiting pacer. A second ventricular-sensing pacer is the so-called ventricular-triggered or synchronous unit. Its circuitry is such that the artificial impulse produced by the generator is timed to reach the ventricle after the ventricle has responded to the natural impulse generated from the patient's own heart pacer. Thus, under stand-by situations the electronic pacer has no effect upon the heart beat. However, should there fail to be an R wave, pacer firing will rhythmically and regularly maintain heart contractions until a natural pacemaker of proper rate and rhythm resumes control of the patient's heart actions.

With ventricular-inhibited demand systems, the pacer remains inactive until failure of receipt of the electrical activity given off by the ventricle in its normal contraction triggers the unit and generates a stimulating impulse. The unit is set prior to implantation so that it will function rhythmically at a fixed rate whenever ventricular sensing impulses fail to be received or when they are received at a rate slower or more rapid than a present range.

The ventricular-synchronous demand pacemaker functions on a different principle. This unit is so designed that the generator triggers an impulse in response to each electric stimulus produced by the natural heart beat transmitted to the unit by the ventricular-sensing electrode and wire. Under normal circumstances with such units, the patient's own ventricle receives stimulating impulses both from the natural heart pacemaker as well as from the artificial heart pacemaker. However, the impulses sent from the artificial pacemaker are so timed as to reach the ventricle at a period in its cycle of contraction (the absolute refractory period) when it cannot respond to this stimulation because its muscle fibers have not as yet recovered from the prior contraction induced by the normally conducted heart beat. Thus, the natural cycle remains undisturbed as long as the heart rhythm and rate are within normal limits. Under such circumstance the artificial pacer, although firing with each heart beat, does not affect the heart beat. However, when naturally induced ventricular contractions fall below or exceed the preset range, the impulse generator of the ventricular-synchronous demand unit starts to fire at a fixed rate. This artificially produces regular ventricular contractions until the abnormal state disappears and spontaneous satisfactory heart rate and rhythm are resumed.

Atrial-sensing pacer systems involve placing the sensing electrode within the right atrial chamber against the right atrial wall. The atrial sensor sends the electrical impulses generated whenever the patient's atrium contracts (as reflected by the P wave of the electrocardiogram). Upon receipt of this impulse, the pacer fires and sends a stimulating impulse via an output wire to the ventricle. Thus the ventricles, although shut off from atrial pacing because of disease or trauma, are enabled by means of the electronic bypass to contract in response to each atrial beat as in the normal situation. The atrial sensing pacemaker is also set so that if no atrial impulses are received through the sensing wire (as when atrial contractions do not spontaneously occur), the generator functions as a fixed rate pacer system. The atrial-sensing pacer thus also protects against cardiac arrest in those patients with paroxysmal sinus block and atrial arrest. And, at the other end of the rhythm scale, when atrial impulses are generated at a potentially dangerous rate as with paroxysmal atrial tachycardia, atrial flutter or atrial fibrillation, the unit again functions as a fixed rate generator and provides artificial ventricular stimulation at a safe preset rate of 60 to 70 beats per minute.

Atrial-sensing units, therefore, have distinct advantages theoretically over fixed-rate systems in that the ventricular heart rate is brought under physiologic control and the heart potentially can adjust its output and response to body needs. The major difficulties with atrial-sensing systems, from a practical point of view, are that thoracotomy is required to ensure adequate fixation of the atrial-sensing electrode and that the complexities of the circuitry and programming of the unit leads to breakdown more often than with other less complicated devices. Atrial-sensing pacers, therefore, in actual clinical practice have only limited practical application and, most often, their use is restricted to young patients with congenital A-V heart block in whom artificial cardiac pacing is indicated.

The standard present-day pacemaker power pack consists of 4-6 zinc-mercury oxide batteries, usually connected in series, to provide an output of about 8 volts. The batteries together with the generator impulse circuitry and electronic components are housed in a sterile epoxy-silicone rubber package about 2.5 cm. thick, 7 cm. in diameter and with weight of about 160 gms. The pacemaker power unit is surgically inserted into a subcutaneous pocket generally in the anterior chest wall beneath the right clavicle where it remains throughout its lifetime.

Because the effective life of batteries is about two to three years with replacement currently often the only way of continuing artificial pacing thereafter, search has been underway for some time for power sources of longer duration. Presently, nuclear-power units with an almost indefinite life or pacers which can be recharged from external sources thus obviating the need of surgical replacement of worn-out units appear to be clinically practical, and the application of these devices is extending. Possibilities also exist for obtaining pacer energy from sources within the body such as might be generated by body fluid chemical changes or from the physiologic mechanical movements of the diaphragm, aortic wall and other body tissues. These are under practical investigation, but presently are too unreliable for practical usefulness.

Impulses generated by the pacemaker power pack and released by the firing unit are transmitted to the heart through fine electrical wires ending in small metal connections called electrodes through which delivery to the ventricular musculature is accomplished. Formerly, these electrodes could be positioned only by direct implantation within the heart muscle (myocardium) or its lining (epicardium) by an operation which opened the chest wall (thoracotomy) to achieve direct exposure of the heart. This major surgical procedure had to be performed under general anesthesia and was associated with a high mortality rate (5-20%) influenced to large extent by the advanced age of the patients who most often needed pacemaker therapy. Thoracotomy also had other disadvantages consisting of increased likelihood of postoperative complications and morbidity and a prolonged hospital stay.

Today, however, the transvenous route of insertion is most often selected when permanent pacemaker implantation is required, and this route is used almost exclusively for temporary heart pacing (as with many patients with acute myocardial infarction in whom standby or actual pacing is necessary only for a few days).

A transvenous pacemaker insertion involves the passage, under fluoroscopic control and most often with local anesthesia only, of a catheter into and through one cephalic vein into the superior vena cava and then into the chamber of the right atrium through the tricuspid valve and into the chamber of the right ventricle. The electrode on the catheter tip is then firmly positioned by pressure against the endocardium of the right ventricle. Once embedded in this manner, the wires from the stimulating and sensing electrodes can be attached to a permanent pacing unit. The site of entrance to the vein is then sutured, and the generator pack placed in a subcutaneous pocket surgically created in the chest wall. The entire procedure usually requires less than one to two hours and necessitates only a short hospital stay with relatively few complications and morbidity since both major surgery and general anesthesia are avoided.

Indications for Permanent Pacing

In the early days of pacemaker therapy, implantation of a cardiac pacemaker was reserved only for patients suffering from complete A-V heart block who were subject to sudden unpredictable bouts of loss of consciousness (Stokes-Adams disease). However, expanding recognition of pacemaker usefulness gradually has extended this therapeutic modality to a variety of recurrent and persistent heart rhythm disorders not satisfactorily responsive to pharmaceutical measures (see Table I) and which might lead to syncope, diminished cardiac output without fully developed congestive heart failure, significant renal, coronary or cerebral insufficiency, or to frank congestive heart failure. Pacemaker implantation in any patient falling within this category could be adequately justified medically so that a plaintiff's contention that he should not have been given a pacemaker would be most difficult to substantiate by corroborative medical expert testimony.

Determination as to whether a given patient should have an indwelling cardiac pacemaker obviously is a medical one to be reached by the patient's primary and consulting physicians depending upon the circumstances of the case and specific medical indications and contraindications of his situation.

Theoretically a cause of action might exist in the situation where a patient with heart disease might well benefit by pacemaker implantation and yet does not have one prescribed. A claim that the failure to prescribe constitutes professional negligence might be establishable in the courtroom because there is widespread growing acceptance by the medical profession that the danger of fatality from unpredictable cardiac arrest in patients with documented persistent complete or changing degrees of heart block often outweighs potential inconveniences, risks or complications of long-term indwelling heart pacing. Thus, a plaintiff would probably be able to obtain expert medical testimony to the effect that in the face of such a diagnosis, with or without symptoms, an absolute indication existed for prophylactic pacemaker insertion as soon as practical. Thus, undue delay in pacemaker implantation or failure of a physician attending such a patient to recommend or to seek pacemaker consultation could become an issue for a jury to decide in regard to the question of professional negligence.

On the other hand, the recognized medical fact that this type of patient admittedly is prone to fainting attacks or to sudden death because of the very nature of his heart disease would probably effectively counter the contention that any given syncopal attack or death for which damages are claimed could have been prevented by prior pacemaker insertion as speculative and conjecture. A plaintiff, thus, although possibly able to establish negligence of a physician in a failure to prescribe a cardiac pacemaker, would probably not be able to support a claim of damages suffered as a direct result of such negligence.

Selection of Pacemaker and Route of Implantation

Continuing technologic advances and increasing entrance of more concerns into pacemaker manufacture now allow considerable latitude in selection of pacemaker instruments and systems (fixed versus non-competitive units and, within non-competitive systems themselves, P wave synchronous, R wave synchronous or R wave inhibiting); of method and route of implantation of the stimulating electrodes (endocardial placement via transvenous insertion or myocardial imbedding via thoracotomy); and of source of generator power (type of battery or soon-to-be available nuclear-powered units, and rechargeable power packs).

Theoretically, in cases of pacemaker failure or other pacemaker malfunction, charges could be entertained that the particular instrument or system chosen by patient's doctor was at fault and responsible for a patient's harm. However, in view of current lack of absolute criteria defining choice or instrument, system design and route of implantation, a medical decision in this regard for a given patient essentially remains a matter of professional judgment rather than an issue of professional negligence to be decided by a legal tribunal, and it is doubtful that a plaintiff's case based on those grounds would be successful.

Pacemaker Follow-Up Care

Eventual pacemaker failure is characteristic and unavoidable for all presently implanted pacing systems. Accordingly, early detection of impending pacemaker failure constitutes a most important component of pacemaker follow-up care since it provides opportunity to replace a failing or otherwise defective unit before the occurrence of a catastrophic situation, as might develop with sudden pacemaker stoppage or runaway pacing.

Cessation of pacing may stem from battery failure in the generator impulse power pack, breakage of electrodes or transmission wires, damage to circuitry, dislodgment of implanted electrodes and increase in pacing threshold of the heart. The clinical manifestations range from Stokes-Adams syncope or sudden death in the pacemaker-dependent patient to minimal or no symptoms in patients in whom continuous pacing is less critical.

Pacemaker cessation may occur suddenly and unpredictably without warning but most often, particularly when due to battery run-down, is preceded by a prolonged period of disordered function allowing detection in ample time for replacement. Failure to provide complete patient instruction for pacemaker monitoring and check for early detection of malfunction, thus could constitute palpable departure from acceptable medical standards of pacemaker follow-up care and comprise an adequate basis for malpractice liability against operating surgeon and treating physician should harm result therefrom.

Unexpected pacemaker failure creates an emergency situation requiring immediate monitoring and, in some cases, transvenous insertion of a temporary pacing electrode to control dangerous heart rates and rhythms until an operation can be scheduled to replace a defective unit or generator pack.

In both medical and legal safeguards, it is recommended that every patient undergoing pacemaker implantation be electrocardiographically monitored post-operatively for a period of at least 24 hours to be sure that the newly-inserted device is functioning properly. Prior to discharge from the hospital a full electrocardiogram and chest x-ray should be recorded to provide comparison data should faulty pacing occur at a later date. Copies of these plus description of the pacemaker (type of unit, manufacturer's name and address, model, serial number, date of insertion, rate setting, and location of pulse generator) should be forwarded to the patient's attending physician. Preferably, copies should also be given the patient to keep with him should he travel any distance from home or from his pacemaker follow-up medical facility. The patient should further be advised to carry on his person at all times an ID card, necklace or bracelet identifying him as a pacemaker patient with name, address and telephone number of his attending physician or pacemaker clinic.

Patients with permanently implanted pacemakers should be followed at regularly scheduled intervals in special pacemaker clinics or by physicians particularly experienced in pacemaker care and their many potential complications. Visits should be spaced in accord with expected times of battery failure indications. Currently, life expectancy of most power packs is 15-30 months with 5 percent chance of failure within the first year and sharp climb in failure rate thereafter. A generally acceptable follow-up schedule would schedule frequent checks of the patient during the first few months after operation, relatively infrequent checks during the early and middle life of the pacemaker at intervals of every 3-4 months, with increasing frequency of checks, bi-monthly or monthly thereafter, as the elective replacement date approaches (30 months for fixed-rate pacers and 24 months for noncompetitive units).

Patients should be alerted to those symptoms and signs which herald pacemaker malfunction and impending failure. The most important are reoccurrence of those symptoms for which the device was originally inserted such as faintness, syncope, fatigue or congestive heart failure, and heart rhythm changes such as undue slowing of the pulse or bouts of tachycardia. Daily pulse rate checks should be performed at home with instructions to report five beat deviations in fixed-rate pacing instruments and tachycardia or bradycardia in demand, noncompetitive units. Specific warning should be given to avoid long trips in the last few months of anticipated battery life. Patients should also be advised to report without undue delay any unusual symptoms or signs, and telephone transmissions of pacemaker action should be done when any question arises for patients under care of clinics equipped to receive and evaluate such data.

TABLE I

CURRENTLY ACCEPTABLE INDICATIONS FOR PACEMAKER THERAPY

I. TEMPORARY ARTIFICIAL HEART PACING

1. Potentially dangerous forms of sino-atrial or atrio-ventricular heart block expected to be transient as with acute myocardial infarction.
2. Compromising paroxysmal rapid heart rhythms not responding to other therapeutic means.
3. Drug-induced severe bradycardia or heart block.
4. Carry-over of patients awaiting permanent pacemaker implantation.

II. PERMANENT ARTIFICIAL HEART PACING

1. Complete atrio-ventricular heart block.
   a. Congenital (with slow ventricular rate)
   b. Acquired from disease or trauma
   c. Asymptomatic or symptomatic with Stokes-Adams attacks, congestive heart failure or low cardiac output leading to renal, cardiac or cerebral insufficiency.
   d. Persistent or intermittent
2. Sinus arrest or sino-atrial block.
   a. Symptomatic episodic or persistent
3. Tachyarrhythmias (supraventricular or ventricular).
   a. Uncontrolled or not preventable by pharmaceutical means
   b. Persistent or recurrent

Risks and Complications of Pacer Implantation

Implantation of pacing electrodes into the heart structures, whether via transvenous or thoracotomy route, and the subcutaneous pocketing of the power pack impulse generator constitute surgical procedures subject, as is most surgery, to complications of anesthesia and to infection and hemorrhage.

Permanent pacemaker insertion also has associated additional hazards of pacemaker failure due to broken wires or damaged power units, perforation of the heart by implanted electrodes, migration and displacement of electrodes to nearby structures, extrusion of the impulse generator from its subcutaneous pocket, pressure necrosis from the weight of the power pack, erosion of the skin overlying wires or generator and painful or otherwise bothersome chest wall or diaphragm muscle contractions.

Transvenous passage of stimulating electrodes to ultimate endocardial position has all risks inherent in the passage of any catheter through venous channels to the heart—particularly fragmentation, breakage, knotting and entanglement of the catheter, perforation of the venous passageways or heart wall, local hemorrhage, thrombophlebitis and air embolism.

And, as pointed out earlier, fixed-rate cardiac pacemakers in patients whose heart rhythm might paroxysmally revert to a normal or conducted mechanism of some sort are associated with an inherent danger of fatality or serious cardiac catastrophe should the competitive rhythms (natural and from the pacemaker) result in rapid heart rates or cardiac arrest as with ventricular tachycardia or ventricular fibrillation.

Defective Pacemakers

Pacemaker malfunction at times may be attributable to the implantation of a faulty instrument. Most often, the fact that the unit is defective becomes apparent within the first 24-48 hours after operation—good reason for close monitoring during the first few postoperative days. In other cases, a faulty unit is suggested where premature battery failure requires replacement of the power pack sooner than the expected life of 24-30 months or when a defective wire or electrode breaks. In such instances the manufacturer and hospital may be enjoined with the operating physician as defendants in a malpractice suit.

To protect himself medico-legally, the surgeon should make sure, when a presumably defective instrument is replaced, that the replaced pacemaker is clearly identified by him in the hospital records as to manufacturer, model and serial number and that it be adequately grossly inspected for obvious defect before return to the manufacturer or other person for internal inspection.

The surgeon should also make sure that a report of the manufacturer's inspection is inserted into the hospital record.

The operating surgeon, if having performed the procedure in accordance with acceptable standards of medical treatment, in selection, testing and implantation, usually will be relieved of liability on grounds that he would have had no reasonable way of determining that the instrument was defective prior to placement within the patient and that he had to rely upon the manufacturer's warranty of a reliable product.

External Causes of Pacer Malfunction

That pacemaker action can be adversely affected by varied external factors to lead to stoppage or runaway pacing is well documented in medical literature.

Failure to warn a pacemaker patient of recognized, potentially dangerous exposures and activities, thus, might well be construed in the courtroom as negligent professional conduct should harm ensue from a foreseeable avoidable cause.

Similarly, the attending physician has a duty to make sure that other physicians, nurses, paramedics and hospital attendants in contact with the patient are cautioned of the presence of an indwelling pacemaker and alerted to the dangers of certain exposures.

Although newer pacemakers offer greater protection against external interference because of better shielding, demand pacemaker stimulation may be slowed, stopped or dangerously speeded by close proximity to a variety of electromagnetic and radio-frequency fields. Potential sources of such pacemaker interference already identified include electric razors and toothbrushes, ignition systems of automobiles, aircraft, motorcycles and lawn mowers, a variety of electric motors and generators, the high voltage transformers of power plants and television sets, electric carrier current or power transmission lines, radar units, microwave ovens and other microwave devices. Pacemaker patients, however, have been reported as safe from ill-effects when passing through the magnetometer units currently employed at airports to detect metallic weapons.

Most instances of electrical interference with pacemaker action do not damage the unit, and the pacemaker quickly returns to its previous performance when the patient is removed from close proximity to the offending source.

Both fixed-rate and noncompetitive pacer action can be adversely affected by certain medical equipment commonly employed in therapeusis. For example, the circuitry of many fixed-rate pacemakers may be damaged by the heat generated by diathermy units and electrocautery surgical cutting instruments. Accordingly, precautions must be taken to avoid close proximity of such units to the pacing device and power pack when pacemaker patients undergo treatment with diathermy, neurosurgical stimulators, electrocautery and high voltage radiation.

Particularly dangerous to pacemaker patients is electrocautery prostatectomy—a procedure common to the age group of many male pacemaker wearers—although recent reports indicate that high frequency electrocautery transurethral operations can be safely performed in pacemaker patients with proper advance safeguards.

The precordial electric currents of electric shock cardioversion have not been demonstrated harmful to the pacemaker patient.

Other hazards against which pacemaker patients should be forewarned include (1) electrode failure possibly associated with too vigorous movement of the upper extremities or to a direct physical load applied to the shoulder area where the electrode catheter is located; (2) damage or disruption of action of the power pack or transmission and stimulating wires and electrodes from direct blows or other physical trauma to the chest wall thoracic cage; and (3) certain types of manual effort such as ironing and sawing wood which subject the muscles of the right arm and chest to prolonged isometric contractions and generate electric impulses which may inhibit pacemaker action.

Conclusions

As has been the case with most major medical advances, the advent of expanding clinical application of the artificial cardiac pacemaker has created many knotty legal issues and problems which the law has been slow to answer definitively. Certain guidance, however, is available from established legal principles concerning the conduct of the individuals involved.

The manufacturer of artificial pacemaker units must exercise all caution to ensure that his units are safely designed, properly constructed, adequately tested, thoroughly inspected and accompanied by complete instructions for insertion, maintenance and follow-up check.

The physician who prescribes a cardiac pacemaker and the surgeon who implants the unit must make sure that their professional skills and professional conduct in this rather highly specialized area of medical and surgical practice satisfactorily measure to those of reputable physicians who employ this therapeutic modality. In each case where a cardiac pacemaker should be considered or is prescribed, the professional conduct of all attending and consulting physicians must be equivalent in judgement, care and skill to the standards set for good and proper medical care under similar circumstances.

The attorney who is consulted by a client seeking potential legal redress for alleged pacemaker problems must make sure that he acquires sufficient knowledge and understanding of cardiac pacers, the medical indications and contraindications for such therapeutic devices, the factors affecting selection of unit and route of placement, the recognized risks and complications and accepted means of avoidance and the established principles of medical follow-up care so that he is in a position to provide proper legal advice and counseling.

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Summary of Actions
Council Meeting
Wednesday, March 19, 1975

I. Attendance

Present in addition to the Chairman, Dr. D. A. Grendon, and the Vice Chairman, Dr. C. W. Johnson, were: Drs. Root, Jr., Spitz, Backhus, Brandon, Nolan, Fabro, Bradley, Hess, Kamens, Ragland, Jr., James, Freedman, Krinsky, Beck, Canzonetti, Harkins, Magram, Mendillo, Eslami, Barrett and Sonnen.

Also present were: Mrs. Lindquist, Mr. Tomat, Mr. Sweeney and Dr. Richards.

Absent were: Drs. VanSyckle, Gardner, Cramer, Granoff, Rubinow, Dambeck, Roch, McGarry, Sadowski and Klare.

II. Routine Business

Approval of Minutes

As published and distributed, it was VOTED to approve the minutes of the meeting of February 20, 1975.

Life Memberships

It was VOTED to approve applications for Life Membership received from the following eligible Active Members:

George G. Fox, 28A Pilgrims Harbor, Wallingford (NH)
James V. Halloran, 184B Apache Lane, Stratford (F)
Leonard C. Scalzo, 924 Noble Avenue, Bridgeport (F)
C. Norton Warner, Jr., North Street, Litchfield (L)
John B. Zielinski, 2573 Main Street, Stratford (F)

Date of Next Meeting

The Chairman set Thursday, April 17, 1975 as the date of the next Council meeting.

III. Old, New and Special Business

Election of Student Member

It was VOTED to elect to Student Membership a Connecticut resident who is enrolled in a U.S. medical school as follows:

Dale Ernest Merrell, RFD No. 1, Bradford Hill, Plainfield, Conn.
University of Pennsylvania—Class of 1978—Pre-Med: Rutgers University
Parent: George G. Merrell

Reports—Fiscal Subcommittee

It was VOTED to act on several reports of the Fiscal Subcommittee as follows:

(a) *Regional Conference, Student National Medical Association:* To approve a recommendation of the F.S. that the sum of $200.00 be contributed to this function of the SNMA to defray the costs of two speakers who are to participate in the program.

(b) *Membership Mailing, Committee on Third Party Payments:* To approve the recommendation of the F.S. that approximately $615.00 be allocated to the budget of the Committee to cover the printing and mailing costs of (a) a letter and brochure promoting use of the AMA Uniform Insurance Claim Form, and (b) a letter concerning recent and current developments in the way the Medicare program is being administered in Connecticut. In a related action, the Council VOTED to approve the texts of both letters for mailing as information to the membership.

Resignations, Appointments, Etc.

CSMS Representative, Connecticut Family Planning Council: It was VOTED to appoint Gary F. Nobert, Avon, to serve as a CSMS representative on the CFPC, replacing LeRoy H. Wardner, Hartford, who is unable to continue in that appointive post.

Communications—J. Alfred Fabro, Torrington

(a) *Responsibilities of CSMS Appointees by the Council to Outside Agencies:* The Editor voiced the opinion that members appointed to serve as CSMS representatives on outside boards, commissions, etc., should receive specific instructions as to what their "future relations" with the Council should be. After lengthy discussion, it was VOTED that members of the Council who serve as liaison members of important outside agencies (commissions, boards of directors, etc.)

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in the state be asked to report verbally on important matters at each monthly meeting of the Council, and that, beginning in April, all new special appointees designated by the Council be notified that reports to the Council should be made, as indicated, on the activities of the agency or group with which they serve.

In a related action, the Council VOTED that the status of the Society's Connecticut Ambulatory Care Study be placed for discussion on the agenda for the next Council meeting and that Frederick C. Weber, Jr., CACS Principal Investigator, and Daniel Hamaty, CACS Project Director, be invited to join the Council at the next meeting to participate in said discussion and to bring the Council up to date on the fiscal and progress status of the Study.

(b) *Annual Report, Editorial Committee of "Connecticut Medicine":* It was VOTED to accept as information, with thanks and commendation, the subject report which had been prepared and submitted by the Editor, J. Alfred Fabro. The report will be transmitted to the House of Delegates on April 30 for consideration and acceptance.

Reports—Committee on Insurance

It was VOTED to act on a two-part report submitted by the Committee as follows:

(a) *CSMS-Sponsored Disability Income Insurance Program:* To receive as information notice that two new benefits have been added to the Program without change in premium. The length of the benefit period is extended from five to seven years, or five to ten years, depending on the basic policy the member carries. A "Rehabilitation Rider" is added which provides funds for education and training when rehabilitation is necessary for conditions due to either illness or accident.

(b) *New Program of "In Hospital Coverage":* To approve the unanimous recommendation of the Committee on Insurance that the Council endorse this new program offered by the Eade Agency for sponsorship by the Society. In brief, the new program will offer up to $80 (in increments of $20) as an indemnity benefit for each day of confinement in a general hospital up to 365 days/yr., and 50% of the selected hospital benefit for each day of skilled nursing home care (for the insured member and spouse but not dependent children) up to quite generous maximums. The policy may be purchased by members of any age and without regard to medical history during a 90 day initial enrollment period, and can be continued for life. The benefits may be used for any purpose elected by the member. Brochures on the new plan will be mailed to all members of the Society in the near future, explaining the details and such exceptions and limitations as may be applicable.

Activity Report—Connecticut Medical Institute, Inc.

Having received a subject report from CMI Staff, the Council noted that "advice, comments or a statement of position from the Council on the selection of a data processing facility" would be welcomed. After appropriate discussion, it was VOTED that the Council recommended to the Connecticut Medical Institute, Inc. that whatever computer facility is selected, it be one that is not controlled by any agency concerned with health care; i.e., that it be one which is on "neutral ground."

Report—Committee on Continuing Medical Education

Having accepted a report of the Committee for filing, the Council VOTED to approve three recommendations contained in the report as follows:

(1) to endorse again the concept as set forth by the Committee on Continuing Medical Education and (2) that the Council recommend to each component county medical association that its Board of Trustees or executive committee place on the agenda of its next meeting this topic of minimum credits of CME as a requisite for continued membership in the respective county association and (3) that each county inform the CSMS Council of any action or recommendation which will be forwarded to the county membership on this topic.

Annual Reports—Standing Committees, Representatives, Etc.

It was VOTED to receive as information a Staff-prepared summary of annual reports submitted (or not submitted) by the committees, representatives and advisors elected by the House of Delegates, and to transmit said reports to the House of Delegates for consideration and acceptance on 4/30/75.

Proposed Subjects for Discussion—Meeting with Welfare Commissioner

Being apprised (by telephone) by Leo P. Giardi, Hartford, chairman of the CSMS Liaison Committee with the State Welfare Department, that a meeting of CSMS representatives with the new Welfare Commissioner, Edward W. Maher, had been arranged for early April, and in response to Dr. Giardi's request for suggested subjects for discussion, the Council VOTED to suggest the following: What percentile of what year is presently being used

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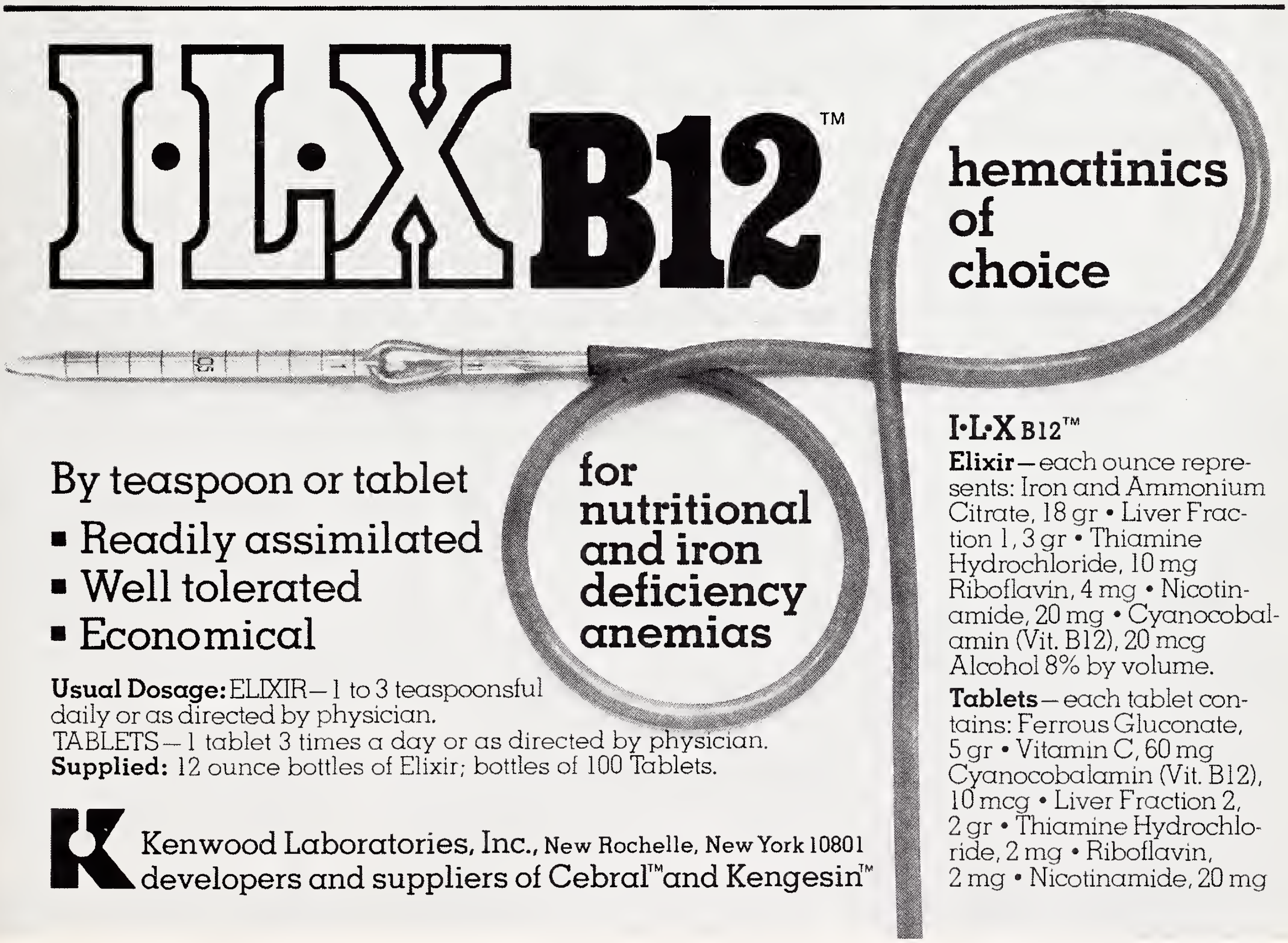
as the basis for Medicaid payments to physicians? Is there any possibility of the payment schedule for MDs being updated at present or in the foreseeable future? What are the current eligibility standards for eligibility to receive Medicaid benefits? Present to and discuss with the Commissioner the "Medicaid Story" publications (1969-70) which reported on the successful experiment with "usual and customary charge" program (1968-69).

Guest Members of Committee on CME

Because the PSROs and CMI will be involved with continuing education for physicians, the Council VOTED to invite the medical directors of the four PSROs and a representative of the Connecticut Medical Institute to be regular "guest members" of the Committee on Continuing Medical Education.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on March 19, 1975. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*



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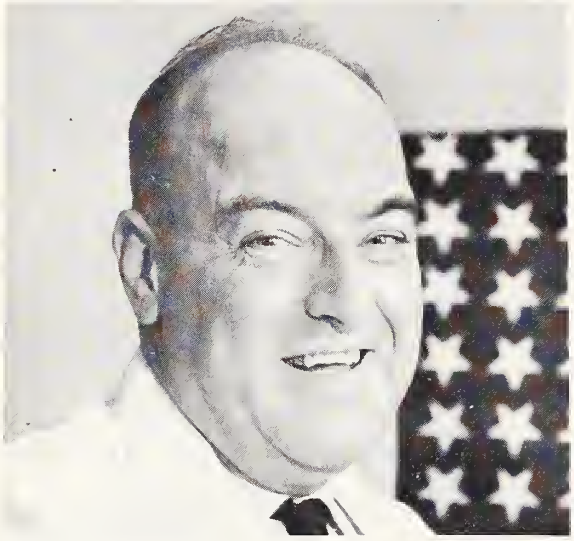
OBITUARY

Paul Winslow Tisher, M.D.
1909-1974

Dr. Paul W. Tisher, senior attending ophthalmologist on the staff of the New Britain General Hospital, died on December 21, 1974, after an illness lasting several years.



Born in Cedar Rapids, Iowa, on September 17, 1909, he was raised and received much of his education in Iowa. He attended St. Ambrose College in Davenport, and received his M.D. from the Medical School of the University of Iowa in 1935. His internship was at the Charles T. Miller Hospital in St. Paul, Minnesota, after which he was the Frank Burch Fellow in ophthalmology at the University of Minnesota.

He established a practice in ophthalmology in New Britain, Connecticut, in 1938, which he maintained until the onset of his illness in 1970.

In addition to his staff appointment at the New Britain General Hospital he was on the consulting staffs of the Bristol Hospital and the Newington Veterans Administration Hospital, and had served on the staff of the Hartford Hospital.

Dr. Tisher's society memberships included the New Britain Medical Society, American Medical Association, Connecticut State Medical Society, Hartford County Medical Association, American Academy of Ophthalmology and Otolaryngology, New England Ophthalmological Society and the Oxford (England) Ophthalmological Congress.

He had been a director of the Connecticut Institute for the Blind, the New England Grenfell Association, and the Medical Board of Project Hope.

He was a volunteer physician to the Grenfell Mission in Labrador and in Newfoundland in 1947, 1951 and 1953, and served aboard the S.S. Hope in Indonesia in 1960-61, and in Ecuador in 1964.

He reached people in many ways, not only through his professional service, but also through his music. He had great talent and overflowing joy and enthusiasm in performing, to the immeasurable delight of his many friends. He had great resourcefulness, filling the needs of his patients at the Grenfell Mission as a physician and dental surgeon and ophthalmologist. The work aboard the Hope was a great challenge to him and he remained an ardent supporter of the project. He combined imagination and persistence in working out the development of plastic lenses, especially for the immediate use of patients who had had cataract operations. These are now used extensively, and have been a major contribution to ophthalmology.

Dr. Tisher is survived by his wife, Dorothy Jane Fluke Tisher, by five children, Mrs. James McCulloh, Mrs. Brendan T. Shea, Mrs. Robert Powell, Miss Dorothy Tisher, and Mr. Paul W. Tisher, Jr., and six grandchildren.

John C. White, M.D.

In Memoriam

Cleary, Harold J., Tufts College, 1929. Dr. Cleary was a practicing orthopedist in the Litchfield area since 1930. Dr. Cleary was a Captain in the Marine Corps from 1931 to 1939. He was a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Cleary died February 8, 1975 at the age of 64.

Douglass, Edmund L., Long Island Medical School, 1916. Dr. Douglass was a general practitioner in the New London area for 50 years. He started practicing medicine in New London in 1920. He was chief of staff of the former Home Memorial Hospital early in his career and was a permanent staff member of Lawrence Memorial Hospital. He was a member of the New London Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Douglass died February 10, 1975 at the age of 83.

Steinmayer, Otto C., Jr., Tulane Medical School, 1950. Dr. Steinmayer served in the U.S. Naval Reserve from 1942 to 1946. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Steinmayer died February 14, 1975 at the age of 54.

WOMAN'S AUXILIARY

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President-Elect
Mrs. Mehadin Arafeh, Middlesex

First Vice-President
Mrs. Mehdi Eslami, New Haven

Second Vice-President
Mrs. Harold Knight, Hartford

Corresponding Secretary
Mrs. Raymond Bopp, Windham

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Package Program No. 13—"Health Education"

At last there is a national auxiliary package program entitled "Health Education." This eagerly awaited addition to the useful package program series* gives ideas on becoming involved in the area of health education in the schools, an auxiliary priority project and a community need.

According to the package's introduction, the purpose of such a program is to ensure that health education is an integral part of our schools' curriculum and that it is being taught in the most effective way by professional and well-trained teachers. To help effect this purpose, the health education packet has background information in development of the program, on encouragement to school boards to become involved, and on educational material for the community. There is information on what health education is, why it is important, how professional health educators function, how existing state programs function and a variety of other subjects. How-to-sheets are included on the following aspects: general activities, auxiliary representatives to schools, educational program, in-service training, research committee and a speaker's bureau. Any or all of these activities may be needed in your community. It is important to find out which areas of service are needed, and to evaluate how much a particular auxiliary can become involved.

The basic requirements of a comprehensive school health education are discussed. The package says that the most important over-all factor in such a program is that it be a planned, sequential program, K-12. It does not consider crash programs, which emphasize particular areas of health, as satisfactory.

Class size and physical arrangements are important to health education along with sufficient funds for instructional materials and adequate teaching staff, who have been prepared in health education. The actual instruction of this staff should focus on aspects of optimal health, with stress on the fact that habits and attitudes formed in early life can aid every facet of adult living. Teachers should be encouraged to explore innovative and creative instructional methods which will involve and interest the student in the subject.

Lastly, the package program states that a good health education curriculum will include the following: consumer health education, dental health education, drug use and abuse, alcohol, human ecology and health, human growth and development, mental health illness, nutrition, personal health, prevention and control of disease, public and environmental health, safety education and disaster survival, and smoking and disease.

American Medical Association position papers, resolutions and legislation on health education are also included in the packet along with an AMA pamphlet, "Why Health Education in Your School?" Lists of motion pictures, college textbooks, health education textbooks, and sources of additional information about health education are in the packet also. This package program should prove an invaluable tool in the school health education area.

**Package programs on Alcohol, Blood Donor, Drug Abuse, Focus on Kids, Health Education, Health Manpower, Immunization, Mental Health, Nutrition, Physical Fitness, Services to Aging, Smoking and Venereal Disease are available for Auxiliary presentation by writing to: Woman's Auxiliary to the American Medical Association, 535 North Dearborn Street, Chicago, Illinois 60610.*

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiry of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511, (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine.*

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

Radiologist: To join group in central Connecticut. Private office practice combined with teaching opportunity at university affiliated hospital. Salary negotiable. Send resume to Radiology, c/o CSMS Physician Placement Service.

Pediatricians: Several opportunities for full and part time positions with the State Office of Mental Retardation. Internist and Family Practitioners will be considered. Full time positions require board certification or eligibility. Salary mid twenties plus housing. Write Sherwin Mellins, M.D., Director of Medical Services, Office of Mental Retardation, State Department of Health, 79 Elm Street, Hartford, Connecticut 06115.

Family Practice: Group in Farmington seeking primary care physician. Possible partnership or coverage for weekends, vacations and emergencies. Send resume to E.H.D., c/o CSMS.

EMERGENCY ROOM PHYSICIAN: Full-service community hospital in suburban setting, with university medical and research centers nearby. Competitive salary for career-oriented individual. Send resume to: Administrator, Meriden-Wallingford Hospital, 181 Cook Ave., Meriden, CT. 06450.

OB/GYN: To join group in Waterbury area. Send resume to P.D., M.D., c/o CSMS.

INTERNAL MEDICINE OR PEDIATRICIAN OR FAMILY PRACTITIONER preferred as Medical Director for Independent Co-ordinate Preparatory School. 890 students. 21 bed infirmary. Experienced nursing staff. Year-round housing on attractive campus. Salary and numerous fringe benefits. Incumbent retires no later than June 1976. Contact W. S. Norton, M.D., Choate Rosemary Hall, Wallingford, CT. 06492.

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

(If no name is listed, contact the Physicians Placement Service)

Anesthesiology: Available July 1975. Board eligible. FLEX. Group or Associate Practice. Completing residency at Beth Israel Medical Center in New York. Bienvenido S. Lee, M.D., 100 East 92nd Street, No. 2A, Brooklyn, N.Y. 11212.

Anesthesiology: Available immediately. Group practice. Board eligible. Completing residency at St. Mary's Hospital in Brooklyn. 34 years of age. Josefina C. Tan, M.D., 14 Branding Iron Lane, Glen Cove, N.Y.

Anesthesiology: Board certified. Presently in practice. Connecticut license through endorsement. Trained in Canada. 37 years old, married. Jong Chill Sun, M.D., 5100 High Bridge Street, No. 14C, Fayetteville, N.Y. 13066.

Anesthesiology: Board certified. Presently in practice. 32 years old. Married. Pennsylvania license. Available now. Roger G. Bucs, M.D., 396 Yorktown Rd., Hershey, PA. 17033.

Anesthesiology: FLEX. Part I for certification completed. Available July 1975. 31 years old. Married. Yogaratnam Gunaratnan, M.D., 14 Second Street, Apt. 4, Hackensack, N.J. 07601.

Family Practice: Available August 1975. Presently in private practice in Ontario. 8 years experience. Trained in London, England. Connecticut license available through endorsement. 32 years old. Married. Solo or associate practice in small community. Lewis Levin, M.D., 63 Hillside Drive, Bramalea, Ontario, Canada L651A5.

E.N.T.: Board certified, 1973. Presently in practice in greater New York City area. Solo practice desired. 42 years old. FLEX. Trained at Long Island Hospital and St. Luke's in New York.

Internal Medicine—Gastroenterology: Associate or Group Practice. Board eligible. Presently GI Fellow at Rhode Island Hospital in Providence. 33 years old. Married. Available July 1975. A. S. Sripathi Karanth, M.D., 331 Prospect Street, Apt. 20, Pawtucket, R.I. 02860.

Internal Medicine (Cardiology): Group or Associate type practice. Board eligible. Trained at Mt. Sinai Hospital in Cleveland and Sinai of Detroit. Available July 1975. 31 years old. Umakant S. Doctor, M.D., 14925 Greenfield Road, Detroit, MI. 48227.

Internal Medicine (Infectious Disease): Board certified in infectious disease. Seeking position as full time chairman of a dept. of internal medicine with teaching and administrative responsibilities. Available immediately. Johns Hopkins and University of Chicago Hospital. Richard Finley, M.D., 405 Bell Downs Drive, Lafayette, LA. 70501.

Internal Medicine (Endocrinology and Hypertension): Available April 1975. Conn. license. Board eligible. Internship and first year residency at Hartford Hospital. Group practice. 37 years old. Married. Wishes to return to Conn. in group practice. Norman J. Kramer, M.D., 7721-A Ivydale Drive, Indianapolis, Ind. 46250.

Internal Medicine: Board eligible. Available July 1, 1975. Solo, group or associate practice in medium sized community. 36 years old. Married. Completing residency. Cheng-Chu Wu, M.D., Bergen Pines County Hospital, Paramus, N.J., 07652.

Internal Medicine-Cardiology: Available July 1975. Board certified. FLEX. Group practice or institutional position. 30 years old. Samuel P. Kumar, M.D., 264-31 Langston Ave., Glen Oaks, N.Y. 11004.

Internal Medicine: Presently in practice. Wishes to relocate from greater New York City area. Connecticut license. 36 years old. Cornell and New York Medical School. E.M.G., M.D., c/o CSMS.

Internal Medicine (Nuclear Medicine): Board certified. Full time nuclear medicine, within commuting distance to New York City. Available July 1975. Herbert A. Klein, M.D., 65-15 Alderton Street No. 3D, Rego Park, N.Y. 11374.

Internal Medicine (Gastroenterology): Board eligible. Available July 1975. Experience in upper G.I. endoscopy, colonoscopy and peritoneoscopy. Presently at Sloan-Kettering Cancer Center, New York. Man-Siak Mak, M.D., 1770 Grand Concourse, No. 2K, Bronx, N.Y. 10457.

Family Practice or Emergency Medicine: Presently in practice in greater New Haven area. Wishes to relocate. Conn. license. A.B.F.P. Yale University School of Medicine, 1970. Yale graduate program. Charter member of Am. College of Emergency Physicians. Write L.R.B., M.D., c/o CSMS.

Family Practice: Board eligible. Immigrant. Available Nov. 1975. Group or Associate. Guaranteed salary or hospital based appointment desired. N.Y. license. FLEX. K. Thekkethala, M.D., 660 E. 98th St., 4-G, Brooklyn, N.Y. 11236.

Ophthalmology: Board eligible. 35 years old. Available July 1975. Head fellow at Guthrie Clinic-Robert Packer Hospital, Sayre, Penna. Ferdinand R. Schwarz, M.D., 1192 Temple Drive, Yardley, PA. 19067.

OB/GYN: Available July 1975. FLEX. Connecticut license by endorsement. Trained at Royal College of OB-GYN in London, U.K., M.J. Shah, M.D., No. 24-3000 Staunton Avenue, Charleston, W.V. 25304.

Orthopaedics: Board certified. Presently in practice. 32 years old. Connecticut license. Available July 1975. Fordham and N.Y. Medical College. Internship and residency at Greenwich Hospital, C.J.R., M.D., c/o CSMS.

Orthopaedics: Desires western Connecticut. Presently in practice. 35 years old. Married. Solo, group or associate practice. Columbia-Presbyterian trained. Diplomate of the N.B.M.E., Lawrence A. Lefkowitz, M.D., 1020 NE 178 Terrace, No. Miami Beach, FL. 33162.

Pediatrics: Interested in Neurology and Neonatology. Board eligible. 33 years old. Married. Georgetown Med. and Children's Hospital in Cincinnati. Available July 1975. Group or associate practice. J.A. Flanagan, M.D., 2873 Fairhill Dr., Cincinnati, O. 45239.

Pediatrics: Board eligible. Available July 1975. 28 years old. Group or associate practice. University of Rochester and Columbia. Available immediately. Jesse M. Mintz, M.D., 1187 Briscoe Ct., St. Louis, MO. 63132.

Pediatrics: Board eligible. Pediatric Hematology and Onocology with General Pediatrics. 47 years old. Massachusetts and California license. Write CSMS.

Pediatrics: Available July 1975. Massachusetts license. Princeton, Tufts Medical and New England Medical Center. Medium or small community desired with group or associate practice. 31 years old. Married, 2 years in Army Medical Corps. Charles J. Okstein, M.D., 30 Beaver Brook Road, Sharon, Mass. 02067.

Psychiatry: Desires part-time position to combine with private practice. Available October 1975. 34 years old. Married. Presently in Air Force. Trained at Yale Child Study Center. Board eligible. Glen L. Bohlke, M.D., 7026 Madelynne Way, Anchorage, AK. 99504.

General Surgery: Available in July 1975. Presently at Mt. Sinai in Hartford. University of Peru. Buffalo General Hospital, New York. Board eligible. Jorge A. Melendez, M.D., 891 West Blvd., No. 103, Hartford, CT. 06105.

General Surgery: FLEX. Board eligible. Presently clinical assistant in surgery at Bellevue Hospital, New York City. Available immediately. 37 years old. Joseph E. Veizagal, M.D., 1675 York Avenue, Apt. 3M, N.Y., N.Y. 10028.

General Surgery: (with General Practice and/or E.R.). Board eligible. FLEX. Pennsylvania license, 31 years old. B.N. Doshi, M.D., 4180 Warrensville Center Road, Cleveland, O. 44122.

Surgery: General: Specializing in surgery of the hand. Completing fellowship. Certified by American Board of Surgery. Available immediately. Lewis Chamoy, M.D., 1139 S. Monaco Pkwy., Denver, CO. 80222.

Surgery: Part I—American Board of Surgery. Available August 1975. RPI and SUNY Downstate, Brooklyn, N.Y. trained. Presently in Navy. Wyman W. Chu, M.D., 825 Bayshore Dr., Apt. 1204, Pennsacola, FL. 32512.

Surgery: Plastic: Board eligible. 36 years old. FLEX. PA. license. Available July 1975. American internship and residency. Roberto Montoya, M.D., 410 Cessna Ave., Charleston, S.C. 29407.

Urology: Board eligible. Available July 1975. FLEX. Residency at Tufts and Beth Israel Medical Center, Mt. Sinai School of Medicine, New York City. 32 years old. Lawrence H. Spiro, M.D., 353 East 17th Street, Apt. No. 9B, N.Y., N.Y. 10003.

Urology: Board eligible. Completed residency at Upstate Medical Center, Syracuse, New York. Presently in practice. Prefers larger or medium size community with group or associate practice. Gerald Frankel, M.D., 6204 Newberry Rd., Indianapolis, IN. 46256.

Urology: Board eligible. Passed part I. Available July 1975. Presently in practice. Desires group practice. 35 years old. Samuel Aronson, M.D., 496 Wintergreen Way, Rochester, N.Y.

Urology: Board certified. Presently in practice. 42 years old. F.A.C.S. Prefers larger city or suburban community. Available late spring or summer. Contact CSMS for more details.

CARE OF THE GERIATRIC AND DISABLED ADULT

Wednesday, May 21, 1975
9 a.m. to 5 p.m.
UConn Health Center, Farmington, Ct.

"Psychiatric Aspects of Patient and Family Management"

"Anti-depressant Drugs, Electroconvulsive Therapy, and the Disabled Heart"

"The Nurse and Physician Roles in Geriatric Care—CHANGE, CHALLENGE and CONTROVERSY"

Sponsored by:
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Registration: $10.00 (including lunch)
To CSMS by May 15.

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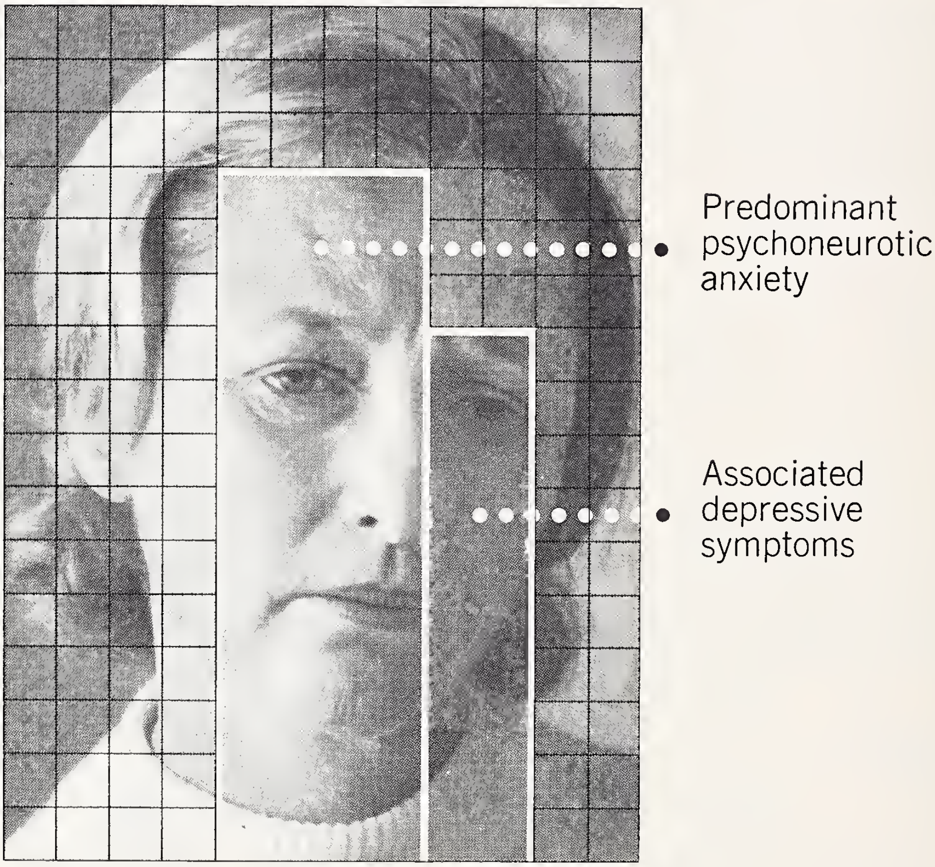
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Lessons from Cardiac Transplantation

Donald C. Harrison, M.D.

During the past six years cardiac transplantation has aroused both the interest of the layman and the sophisticated physician. While most cardiac programs have ceased to perform this procedure, at Stanford we have continued our active transplantation effort as a major scientific endeavor for medical and surgical cardiologists. Moreover, the "fallout" of scientific information from the program has added immensely to our understanding and abilities to diagnose and treat cardiac disease in a much broader context. First, let me summarize our transplantation program results and then illustrate several areas of "fallout."

At Stanford we have performed 78 cardiac transplants since January, 1968.[1] [2] We continue at the rate of approximately 1 transplant per month, and at the present time have 27 surviving patients. For those patients who survive for more than 3 months following the procedure, there is an actuarial survival of 74% at 1 year, 66% at 2 years, and 44% at 3 years. Seventy percent of the patients undergoing cardiac transplantation at Stanford have had coronary artery disease as their primary lesion and 30% cardiomyopathies or rheumatic heart disease. At present our criteria for selecting potential cardiac transplant recipients include young patients (under 55), with end-stage heart disease no longer treatable by conventional medical and surgical means, who have adequate hepatic, pulmonary, and renal function to permit uncompromised survival, who are psychologically well suited for the procedure, and who have no other life-limiting diseases. We screen between 30 and 40 patients per year.

While I believe that cardiac transplantation itself is an important area for future investigation and one that will be practical in a small number of patients with end-stage cardiac disease in the future, I wish now to emphasize several areas in which the cardiac transplantation programs have taught us other medical and surgical lessons during the past five years. Clearly a successful program requires a major team effort in an institution with expertise in several areas. These include major cardiovascular surgical programs, cooperation from the neurologists and neurosurgeons, a dedicated psychiatric and psychiatric social worker staff, an expert medical cardiology group, and hematologic and immunologic support for the overall program. All of these have existed at Stanford and account for the continuation of the program as it exists and its success to date. All of these disciplines have benefitted enormously from the collaboration engendered and have experienced some element of scientific advance in a related area. I could emphasize a large number of areas in which we have learned important medical and surgical lessons from transplantation, but will stress only four specific areas. These have been chosen because of their general medical interest and because of the importance of the underlying problem to which they relate.

1. *Accelerated Atherosclerosis:* In the first six long-term survivors of cardiac transplantation who later expired, a major form of coronary atherosclerosis was detected in the new heart that had been transplanted into these patients. This atherosclerosis appeared to be an accelerated form of the standard variety of coronary artery disease which we observe in thousands of patients each year. Pathologically, the lesions consisted of deposits of lipids and cholesterol in the walls of blood vessels and the migration of cells from the middle part of the wall of these blood vessels to the inner wall of the blood vessel producing major obstructions in the arteries. Fibrosis, platelet and fibrin deposits and ulcerated lesions typical of coronary atherosclerosis were found widely in all coronary vessels in these patients. This appeared to be an accelerated form of atherosclerosis since it did not occur with this severity in other blood vessels in these same patients. We developed the hypothesis that this was due to damage of the inner wall of the transplanted heart's blood vessels by immunological reactions and the incorporation of abnormal blood lipid (fats) and lipoproteins in these damaged vessel walls. Indeed, it appears that the length of exposure and the intensity of each of these factors relate closely to the degree of accelerated form of atherosclerosis which has been observed. We believe that studying these lesions and the pathophysiology of their development may permit us to understand the usual variety of coronary atherosclerosis, which is the leading killer in the United States today, affecting more than 700,000 patients each year. While it is too early to determine whether or not other immunological processes may damage the inner wall of

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DR. DONALD C. HARRISON, William G. Irwin Professor and Chief, Cardiology Division, Stanford University School of Medicine, Stanford, Calif.

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blood vessels leading to the deposits of blood fats and finally to coronary atherosclerosis, we believe that in some patients this is the pathophysiology which occurs. We know that other factors which damage the endothelium of blood vessels can lead to accelerated atherosclerosis. Irradiation, certain chemicals such as allylamine, and viruses can probably lead to these initial injuries. We believe these types of initial injury may occur many years earlier and lead to initiation of the atherosclerotic process. Continued work with this model may well shed important light upon the question of coronary atherosclerosis.

At the present time we have developed means of preventing this rapidly progressive atherosclerosis in the transplant patient by treating him with drugs which prevent the aggregation of platelets on the damaged inner blood vessel wall, by reducing the fat in the blood of the patient by diet and drugs, and by carefully preventing the number of rejection episodes that each patient might be undergoing early in his course after receiving the new heart.[3] We are particularly attempting to prevent early rejection episodes.

2. *Physiologic Correlation with Pathologic Abnormalities During Rejection:* When the rejection process occurs in the transplanted heart, certain physiologic abnormalities occur in the heart. By studying carefully each patient having a transplantation rejection episode, we have been able to conclude that changes in electrical activity in the transplanted heart developed early, that this is associated with swelling or edema in the wall of the transplanted heart, that a stiffening of the wall occurs with infiltration of lymphoctyes (white blood cells), and that as cell death (necrosis) takes place, marked mechanical abnormalities in the function of the transplanted heart occur. By utilizing a series of non-invasive measures, including echocardiography (new sonar techniques for diagnosing heart disease), phonocardiography (a study of cardiac sounds), and improved techniques for recording the electrocardiograms from the inner surface of the heart, earlier recognition of rejection and its reversal with drug therapy has been possible. Correlation of such pathologic events with abnormal physiology in the cardiovascular system represents a significant opportunity to validate some of the techniques of non-invasive cardiovascular measures which have been developed. We have validated many of our ultrasound techniques in this model group of patients.[4]

3. *The Development of a New Method of Cardiac Biopsy:* In order to study the early pathologic steps in cardiac rejection, it appeared important to develop a method of biopsying the human heart on a serial basis. We have modified a biopsy technique developed in Japan and have developed our own cardiac biopsy equipment which is mounted on the tip of a cardiac catheter.[5] The catheter can be introduced percutaneously into the jugular vein. It can be advanced through the vein in the neck into the heart under fluoroscopic control and small pieces of the inner layer of the heart muscle can be taken from several areas for study with electron microscopy and new histochemical staining techniques for proteins, enzymes, etc. This has proven to be a safe method to biopsy the inner surface of the heart and is now routinely used in all cardiac transplant patients. We biopsy all transplant patients several times and, in fact, one patient has been biopsied 27 times. More than 500 total biopsies have been performed at Stanford.

Perhaps the most important advance which will occur will be the utilization of this technique in studying other forms of heart disease. At the present time, we are doing biopsies in patients with muscle abnormalities of the heart and attempting to relate them to other muscle abnormalities in the skeletal muscle groups throughout the body. In addition, we have studied a group of patients who, by medical history, have all of the clinical findings of coronary artery disease, but at the time of coronary angiography and catheterization have normal studies. Pathologic study of the muscle biopsy from these hearts demonstrates abnormalities in small blood vessels. These abnormalities are in the lamina propria and the lesions in blood vessels are associated with ischemic muscle cells. The suggestion that these individuals have deficiencies in transporting nutrients and oxygen to the muscle cells has been advanced by us as the cause of these patients' symptoms. Clearly, this may provide us with an understanding of a great many patients who have cardiac symptoms, but in whom it is not possible at this time to demonstrate cardiac pathology. Other detailed biochemical, hemodynamic, and electrophysiologic studies are being carried out in these patients.[6]

4. *An Understanding of the Control Mechanisms in the Transplanted Heart:* Although for years we have recognized that the nervous control of the heart was essential for normal function, few studies in man were carried out. Since the transplanted heart is severed from all nervous connections and these do not grow back, we have been able to study the effects of the nervous system on cardiac electrical impulse generation and transmission, upon the contractile properties of the cardiac muscle, and upon the action of drugs commonly used to

treat heart conditions.[7,8] We have studied the reflexes which permit the control of the heart by the brain since these are not operative upon the transplanted heart, but continue to operate on the residual atrial portion of the heart of the original recipient which is left in place. Using sophisticated electrical techniques, including catheters with multiple sites for electrical recording (His electrogram), we have studied the direct effect of antiarrhythmic drugs in the transplanted heart and have demonstrated that they alter conduction through the atrioventricular node, but that many of their primary actions are on the nerves that innervate the normal heart and that their actions are significantly altered in the heart which has been severed from its original nervous control. The electrophysiologic action of such important drugs as digitalis have been clarified by our studies.

Summary

Thus, although the saga of cardiac transplantation in itself is an exciting one and one which justifies much attention, the "fallout" in terms of medical and surgical lessons which we have learned because of our ongoing program in transplantation continues to point the way toward a better understanding of coronary heart disease, of drugs which affect the heart, and of new techniques which permit a better diagnostic procedure in patients with other forms of heart disease. We continue to be excited about our program and will push forward with all of these leads, knowing that scientific advances are indeed possible utilizing the transplanted heart as a model for other studies. Perhaps the "fallout" from transplantation will be of greater importance than the original operation.

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The AMA's New NHI Plan

The Comprehensive Health Care Insurance Act was introduced in Congress late in April. It builds on the existing structure of employer-employee group health insurance plans. Each employer would be mandated to provide comprehensive and catastrophic benefit coverage and pay at least 65% of the cost. Employees would not be compelled to participate. Under the plan the self-employed and unemployed could purchase qualified private health insurance, with the government paying all or part of the premium, depending on income tax liability. Medicare beneficiaries could purchase supplemental insurance, with the government assisting people with limited incomes. Medicaid would be eliminated. Small businesses that would be burdened by the mandated plan would receive assistance from the government. State governments would regulate insurance, subject to federal guidelines established by a 15-member Health Insurance Advisory Board.

Rheumatoid Disease, An Overview

Robert B. Zurier, M.D.

Abstract—The approach to the patient with rheumatoid disease (RD) should be comprehensive and not simply an attack on inflamed joints. Diagnosis of RD should not be made casually as it raises the spectre of crippling. Once the diagnosis is established, the physician can be encouraging since in the majority of patients joint deformities develop to only a modest degree. New and even overwhelming problems often are introduced into the patient's life by the disease and these must be discussed frankly and thoroughly. Daily exercises should become a way of life for the patient with RD. Salicylates remain the mainstay of symptomatic treatment and should not give way to more potent drugs without being given an intensive trial in which the highest possible doses are used. Gold therapy often results in dramatic suppression of arthritis and appears to retard destruction of bone. Close cooperation between physician and surgeon will help to insure that should operative treatment become necessary, it will be carefully considered and properly timed.

Rheumatoid arthritis (RA) is a disease of unknown etiology and unpredictable course. Although arthritis is the most frequent and prominent manifestation, it is a generalized illness involving many systems and perhaps is more correctly termed rheumatoid disease (RD). Females are more commonly affected, probably in a ratio of approximately 2.5:1. Although maximum incidence of onset is in the fifth decade (40-50 years), no age group is exempt. The pattern of onset is variable. There may be acute or insidious onset of polyarthritis or disease may be confined to one joint (monoarticular) for a prolonged period, sometimes years, before becoming polyarticular. In addition, presentation may be characterized by recurrent episodes of polyarthritis with periods of complete remission. A period of observation is often necessary before a firm or even correct presumptive diagnosis of RD can be made. The American Rheumatism Association criteria[1] for diagnosis are useful. However, patients often present with an incomplete pattern of clinical features or may appear to "meet the criteria" yet in fact have a different inflammatory arthropathy. Thus there need not be a rush to judgment. The physician should not be reluctant to explain to a patient with arthritis that a diagnosis cannot be made when that is in fact the situation. Lack of a definitive diagnosis does not preclude adequate therapy to relieve symptoms, but an improper diagnosis may lead to unnecessary, even harmful, treatment and a good deal of emotional trauma for the patient. Hopefully, as medical knowledge increases, the numbers of patients with arthritis of unknown type will diminish.

Once diagnosed, the patient deserves from the physician a discussion of the life problems introduced by rheumatoid disease and help in devising a comprehensive treatment plan. Failure to establish a satisfactory relationship and obtain the patient's confidence early in the course of treatment is perhaps the main reason why patients turn to practitioners of unethical medicine and quack remedies. It is not possible to predict reliably the course that rheumatoid disease will follow in an individual patient. It is a disease characterized by spontaneous exacerbations and remissions. Nonetheless, some generalizations can be made: 1. 20% of patients have short-lived activity of joint disease which remits without residua; 2. 25% have joint disease which remits to leave only mild or moderate residua; 3. 45% have persistent activity of arthritis punctuated by exacerbations and remissions leading to a variable degree of progressive deformity. 4. 10% have severe disease leading to disability which restricts the patient to a bed or wheelchair life. Thus it is possible to be encouraging. Too many patients consider that the diagnosis of rheumatoid arthritis is a passport to the wheelchair.

Etiology

The cause of rheumatoid disease is not known. However, studies of the mechanisms of inflammation have shed some light on pathways which might lead to joint tissue injury.[2,3] The accumulating experimental evidence favors the idea that, in the rheumatoid joint, antigen(s) combine with antibody(s) to form immune complexes which activate the complement sequence, generating a variety of biologically active materials, including some with potent chemotactic properties. These call forth into the articular cavity polymorphonuclear leucocytes which are attracted to and ingest the immune complexes. During phagocytosis the neutrophiles discharge a variety of lysosomal (granule) enzymes

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DR. ROBERT B. ZURIER, Division of Rheumatic Diseases, Department of Medicine, University of Connecticut School of Medicine, Farmington.

which are capable of producing the proliferative (synovium) and destructive (cartilage and bone) changes characteristic of rheumatoid arthritis.

Clinical Features

Perhaps the most common characteristic symptom of RD is the painful stiffness that is present on waking in the morning and wears off gradually during the day with activity. This morning stiffness is one of the most useful indices of rheumatoid activity. Morning stiffness should last more than 30 minutes to be accepted as significant.

The most commonly affected joints are the metacarpo-phalangeal (MCP), proximal interphalangeal (PIP) and the lateral four metatarso-phalangeal (MTP) joints. Wrists, knees, shoulders, hips, elbows, ankles and mid-tarsal joints are often involved. The temporo-mandibular joint is affected in about 25% of the patients; temporary limitation of motion is not uncommon but ankylosis is rare. With shortening of the mandible, seen most often in juvenile rheumatoid arthritis, the lower teeth shift behind those of the maxilla giving a bird-like appearance. Rheumatoid involvement in the cervical spine is usually confined to the C1-4 segments.

Synovial hypertrophy and effusion produce the typical swelling, which, in the fingers causes a spindle-shaped appearance. In the hands, swelling usually is confined to MCP and PIP joints. Early synovial swelling of the wrist is highly characteristic and is a valuable sign in distinguishing rheumatoid from degenerative joint disease. Persisting or recurrent effusions result in stretching of the joint capsule and ligamentous laxity which lead to an unstable joint and subluxation. The most common joints to become subluxed are the MCP (palmar subluxation) and MTP (dorsal subluxation) joints. Anterior subluxation of the wrist may also occur.

Several deformities of the hands are characteristic of RD. Ulnar deviation at the MCP joint is common, but by itself produces very little functional disability. Hyperextension at the PIP and fixed flexion of the DIP is termed "swan neck deformity." The earliest sign of incipient deformity of this type is observed when the patient makes a fist: the interphalangeal joints remain extended until late in the maneuver in contrast to the normal pattern in which fingers are promptly rolled up from the distal end. The Boutonniere (button hole) deformity is the opposite and due to PIP joint protrusion through the extensor expansion, the two halves of which slip forward. Thus attempts to extend the joint produce PIP flexion with DIP extension. The crippling process which interferes most markedly with function is the flexion contracture, the greatest problems being deformity (contracture) at the hips and knees.

Extra-articular Features: Constitutional symptoms—fever, weight loss, malaise—may accompany, and occasionally precede the arthropathy. Depression, a result of the newly encountered persisting generalized symptoms in an active young person, may be the presenting complaint. Lymphnode enlargement is a common feature of active disease. This involves, particularly, nodes draining inflamed joints. The subcutaneous nodule occurs in approximately 25 percent of patients at some time in the course of their disease, often appearing and disappearing rapidly and mysteriously. The most common site for the nodule is over the extensor surface of the ulna at the elbow. Other pressure points where they occur include the Achilles tendon and ischial tuberosity. They vary in size from 3 mm to 3 cm diameter and form a firm non-tender mass. They are found only in patients with positive serum tests for rheumatoid factor and their appearance in persistently seronegative patients demands biopsy. Other extra-articular features include anemia (usually resistant to iron therapy), vasculitis (usually associated with longstanding seropositive severe disease in males), carpal tunnel syndrome, pulmonary fibrosis. Whereas uveitis is well recognized in juvenile rheumatoid arthritis (JRA), it is not a feature of adult rheumatoid disease. Common in adults, however, is the sandy gritty sensation in the eyes characteristic of keratoconjunctivitis sicca due to reduced lacrimal gland secretion (constituting part of Sjogren's syndrome). Felty's syndrome is defined as the association of RD, splenomegaly and neutropenia, though the degree of splenic enlargement and of white count reduction can vary substantially from month to month without apparent relationship to each other. It usually occurs late in the disease, and is often associated with chronic leg ulcers and an increase in bacterial infections.[4] Splenectomy is usually performed in patients suffering recurrent or chronic infections.

Laboratory Investigation

Determination of the erythrocyte sedimentation rate (ESR) by the Westergren method is an extremely useful investigation, as it reflects inflammatory activity. A normal ESR, however, does not exclude disease activity.

Rheumatoid factor (RF) is an immunoglobulin (usually IgM) found in the serum of approximately 80% of patients with RD. It appears to be an antibody to altered immunoglobulin G (IgG) and is detected by adding the patient's serum to an inert marker (usually latex particles) coated with rabbit or human IgG. RF is not specific for RD. It is present in about 5% of the population at large and may occur during the course of a variety of diseases, notably bacterial endocarditis (in 50% of patients) and hepatitis. Nonetheless, it remains a valuable test in the evaluation of inflammatory joint disease. Diseases such as psoriatic arthritis, Reiter's syndrome and ankylosing spondylitis frequently resemble RD. They are, however, "seronegative arthropathies." Thus RF, characteristically present in RD, helps to separate these diseases from RD.

Radiology

The *basic* X-rays required for assessment of a patient with an inflammatory arthropathy are PA view of both hands on one plate, an AP view of both feet on one plate, an AP view of the pelvis (including hips and sacroiliac joints). Further radiology may be requested in order to evaluate particular joints. The first radiological signs of RA are nonspecific and reflect the inflammatory process. They consist of swelling of tissue surrounding the affected joints and rarefaction of the adjacent bones. As cartilage is damaged and eroded the "joint space," which represents the thickness of the two layers of articular cartilage on adjacent bone ends, becomes narrowed. Narrowing is first seen in the small joints of hands and wrist but can affect any synovial joint. An erosion is a bone cyst that communicates with the joint cavity through the bony cortex and is the radiological hallmark of RA. Erosions are seen in their most characteristic form in small joints of hands and feet. The correct radiographic projection is necessary to demonstrate the breach in cortical bone, without which the lesion is termed a cyst and not an erosion. In the hands, erosive changes are most common in the MCP and PIP joints. Carpal erosions are not uncommon and the ulnar styloid process is frequently eroded early in the course of the disease.

Treatment

Rest

It is generally agreed that rest is of value in the presence of very actively inflamed joints. Hospitalization for several days can be useful if it provides emotional as well as physical rest and assures use of full anti-inflammatory therapy. It is not always necessary to rest the entire patient and splints, judiciously applied, can alleviate inflammation, relieve pain, combat deformity and enhance function. Wrist splints are probably the most useful and commonly applied. Strength and agility of the hand seem to depend more on the integrity of the wrist than of the small joints of the fingers. Thus even with mutilating forms of arthritis many patients retain the ability to clean, feed and dress themselves. Painful unstable wrists threaten this independence. It is clear that cooperation between physician, surgeon and physical therapist will result in the best possible care for the patient.

It is a good idea to recommend that patients place a board (3/4 inch plywood) under a firm mattress. The board should be shorter by two inches in each direction than the mattress in order that whoever makes the bed avoids getting skinned shins. Sagging mattresses, by virtue of making muscles work to support the body, promote muscle pain and fatigue.

Physical Therapy

The most important modality in the physical therapy of rheumatoid arthritis is exercise. Therapeutic exercises are designated to preserve joint motion, muscular strength and endurance. The duration and frequency of exercises should be limited by the level and duration of pain persisting after completion of the exercises. Pain lasting more than an hour after exercise indicates that the exercise has been too vigorous and should be decreased but *not* discontinued. A proper balance of rest and exercise is sometimes difficult to achieve but should be pursued. The exercise program should be part of the patient's daily activities at least until remission of the disease has occurred and muscle and joint function have recovered.

Drug Treatment

Salicylates remain the mainstay of symptomatic treatment and should always be used as the drug of first choice. Salicylates have anti-inflammatory as well as analgesic effects but doses of at least 4 gm. daily (12-5 gr. tablets) must be used to obtain reduction in joint swelling. Aspirin therapy should not be regarded as ineffective until the highest possible doses have been tried. For example, whereas 16 aspirin per day may produce moderate elevations in plasma salicylate levels, in some patients an additional two to three tablets daily may well cause the salicylate level to plateau at a therapeutic level and cause dramatic relief of swelling and pain. The drug should be administered in adequate levels with least toxicity. The first sign of salicylism is usually tinnitus. When this occurs the dose is reduced to the amount immediately below that which will cause tinnitus (usually decrease of 1-3 tablets daily). In general, plasma salicylate levels of about 20 mg. percent are considered therapeutic. Children tolerate higher (about 30 mg. percent) blood levels but must be more carefully monitored for evidence of toxicity. Dyspepsia is a troublesome side effect of aspirin therapy but usually can be avoided if the patient takes the aspirin with meals. Fortunately, aspirin is absorbed despite the presence of food in the stomach. A major disadvantage of salicylate preparations is their irritating effect on gastric mucosa which results in blood loss from the gastrointestinal tract of 4 ml. daily. Choline Salicylate is reported to not cause as great a blood loss.[5] Absorption from the gut of enteric coated aspirin is not predictable and plasma salicylate levels should be monitored when it is used. A larger bedtime dose of aspirin, despite absence of symptoms, may prevent to some extent painful morning stiffness. It is important to teach patients that aspirin must be taken regularly daily and not only when joints are painful.

Indomethacin is an anti-inflammatory agent which was introduced into the United States in 1965. Some patients find it more effective than salicylates. Concurrent administration of aspirin and indomethacin often results in a decreased serum level of indomethacin due probably to its decreased absorption from the gut.[6] Thus combined aspirin-indomethacin therapy is not recommended. About one-third of patients note at least one undesirable side effect. Indigestion is the commonest complaint and can be minimized by taking the drug with food. The incidence of gastrointestinal bleeding is about the same as with other anti-inflammatory drugs. Frontal headache is common and often can be avoided by starting patients on a low dose (25 mg./day) and progressing to therapeutic levels (75-150 mg. daily) over two to three weeks. Indomethacin and aspirin both inhibit prostaglandin synthesis and it has been suggested that might explain their anti-inflammatory effects.[7] The precise role of the prostaglandins in the inflammatory response is not clear.[8]

Phenylbutazone and its analog oxyphenbutazone have been used in treatment of rheumatic diseases for more than 20 years. They are more effective in treatment of gout and ankylosing spondylitis than in rheumatoid disease. In RD they are most effective when articular symptoms develop rapidly. The recommended dose is 100 mg. three times daily after meals or with milk. Common reactions include edema, nausea, vomiting, dermatitis, anemia and leukopenia. When used concomitantly with anticoagulants the prothrombin time is prolonged and bleeding may be severe.[9] Phenylbutazone can be administered, if necessary, for long periods of time with reasonable safety provided the patient is observed carefully.

Results of a controlled double blind study[10] carried out over a 28 month period indicate that gold therapy for RA retarded progression of the disease in 8 of 13 patients, as shown by radiologic analysis (evaluation of joint space narrowing, subchondral cysts, osseous defects and ankylosis). Cyclophosphamide is the only other drug which has been shown to slow progression of RA as measured by radiography.[11] Atomic absorption spectrophotometric analysis now makes practicable the repeated estimation of gold in serum and urine. It is not clear, however, whether such measurements will be useful in allowing treatment to be tailored by varying the dosage according to the concentration of gold in the serum of the individual patient.

Although their mechanism of action is not clear it appears that gold salts are in fact "anti-rheumatic." Should gold not be used then as soon as the diagnosis is made of rheumatoid disease? The answer is no precisely because of the inability to accurately predict the course of the disease. It is, however, in the early active stage of disease that gold can be of most benefit. If joint inflammation is not controlled by aspirin and if the disease is observed to advance steadily and involve joints not previously affected it seems correct to consider treatment with gold. A typical plan is to give weekly intramuscular injection beginning with two test injections of 10 mg. each, then 50 mg. weekly to a total of 500 mg., the usual amount necessary to produce a clinical response. If the response is encouraging injections are continued until a total of 1000 mg. is reached, at which time 50 mg. is given every second and finally every fourth week. As assays for gold in biological materials become readily available it is possible the dosage schedule for gold may become more rational and effective.

The administration of gold salts may be associated with a number of serious toxic reactions including albuminuria, skin rash, bone marrow suppression and stomatitis. The rash is characteristically eczematous and pruritic. It may be preceded by an eosinophilia and develop into an exfoliative dermatitis. A metallic taste may precede stomatitis and the discrete inflammatory lesions which develop in the oral mucous membranes may ulcerate. Although rare, an acute allergic reaction may follow the initial injection. Considering that the severity of reaction may be dose related some rheumatologists begin treatment with a 1 mg. test dose. Every injection should be preceded by inquiry about pruritus or skin rash, examination of urine for albumin and complete blood counts including platelet counts (bone marrow suppression may present as an isolated thrombocytopenia). When gold therapy is discontinued at the first sign of an adverse reaction serious problems can usually be avoided. Skin rash will usually respond to topical or, if necessary, systemic corticosteroid preparations.

The chloroquines are the *antimalarial drugs* which have the most definite anti-rheumatic effect.[13] The derivative most widely used is hydroxychloroquine (Plaquenil). The usual dose is 200 mg. daily and, generally, response is not seen until the drug has been used for two months. The drugs have mild long-term anti-rheumatic effects, are usually used in patients intolerant to gold therapy and may be safely added to salicylates. Greatest concern in use of the compounds centers on ocular complications, including the possibility of retinopathy and corneal deposits which may result in blurred vision and/or halos. The retinopathy, not uncommon during treatment of patients with systemic lupus erythematosus,[14] is rare during therapy for rheumatoid disease and appears to be dose and time related. The precaution of frequent (every six months) ocular examination is recommended.

Glucocorticosteroids are the drugs most commonly used to suppress undesirable immune or inflammatory responses. Although there exists a vast body of descriptive detail dealing with these steroids, relatively little is known about the exact mechanisms whereby their anti-immunologic and anti-inflammatory benefits are achieved. The side effects of steroid therapy are well-known however, and it is evident that the drugs should not be used casually. The special danger in the long-term use of moderate doses to achieve anti-inflammatory effects is the insidious onset of infection culminating in overwhelming sepsis. However, joint inflammation and incapacitating symptoms may persist despite conservative treatment and even after a trial with gold or antimalarials. At that point it may be necessary to use these potent drugs. Corticosteroids should be given in addition to, rather than instead of, aspirin. Doses are kept to the minimum that will produce adequate relief. The aim is to ameliorate rather than suppress symptoms since the latter may require unacceptably high doses. A disappointing aspect of corticosteroid therapy is that the same dose that in the first days of therapy produces apparently miraculous improvement, later achieves much less, despite increasing evidence of side effects. An attempt should not be made to enhance or extend this “steroid honeymoon” by using unnecessarily high doses of the drug. There is evidence[15] that alternate day administration of corticosteroids is useful and may result in less adverse effects.

The *immunosuppressive* (cytotoxic) agents are being used in severe rheumatoid disease. Early reports are encouraging[11] but adverse effects are not uncommon. As with the corticosteroids, the patient’s vulnerability to infection must be kept in mind. There is evidence that patients treated with cyclophosphamide (Cytoxan) may sustain fewer new bone erosions than comparable patients treated in a more traditional manner. The place of cytotoxic drugs in treatment of rheumatoid disease remains unclear.

Surgery

Dramatic advances, including total joint replacement, have been made in recent years in the surgical treatment of rheumatoid arthritis. These are reviewed elsewhere.[16] [17] The choice of operation and its timing are matters requiring the most careful consideration by physician, surgeon and patient. Contrary to what has been thought previously, it is not necessary to suppress inflammation completely to obtain a good functional result from surgery. Synovectomy is now popular for the second time in this century. It seems logical to remove the proliferative synovial membrane which as pannus forms a mantle over and appears to erode cartilage. A multicenter evaluation of early synovectomy in RA is being sponsored by the Arthritis Foundation and analysis has been reported of a three year observation period.[18] In terms of pain, tenderness, swelling, effusion and function, synovectomized joints (knees and hands) were significantly superior to the controls at the end of one year. At the end of three years all these differences had disappeared. Nonetheless, there is still a place for synovectomy in well selected joints adaptable to such surgery, especially to relieve intractable pain. There is general agreement that early synovectomy of the wrist can be a rewarding procedure since dorsal tenosynovitis of the wrist is not uncommon in RA and can be associated with tendon rupture.

Special Problems

Sexual Problems of the Arthritis Patient

Arthritis superimposes on the normal problems of sexual adjustment the compounding factor of illness and disability. Arthritis involvement of the hip is the disability most likely to provide a direct mechanical barrier to sexual intercourse. Degenerative disease of the hip is the most common problem, but pain and limited motion of the hip not infrequently occurs in younger patients with rheumatoid disease. Flexion contractures in adduction usually develop and either prevent abduction and external rotation of the hip or produce severe pain when such motions are attempted. The customary frontal approach in sexual intercourse requires, for the woman, abduction of the thighs and external rotation of the hips. This “missionary position” is so favored in our culture that many patients are not aware that other positions are possible. (and indeed preferred in other cultures). Thus the simple expedient of explaining variant positions and techniques may allow patients to remain sexually active. Physicians should familiarize themselves with positional variations to counsel more effectively. If neither the patient’s nor the physician’s reticence can be overcome reference manuals may be used, but most patients welcome an invitation to discuss their sexual problems with physicians. Pain often inhibits sexual activity and is usually relatively easy to combat with a combination of medical and physical measures. Application of moist heat in the form of warm baths or showers or compresses to affected joints before any activity, including sexual activity, can reduce the gelling that causes pain and impedes motion. Range of motion exercises to limber up should follow. Patients may at first consider such a program (which they have already found to be helpful before other activities) to preclude the spontaneity they feel necessary to sexual activity. Nonetheless, it may make the difference between satisfactory sexual expression and its total avoidance. In addition, the preparations can become an integral part of sexual activity. It is often necessary, of course, to speak with and counsel the patient's sexual partner as well. The only way to find out if a patient considers sexual activity important is to ask. To prejudge is to misjudge. The seemingly most unlikely patients need counseling. The best guide to a patient's sexual adjustment is an analysis of the pre-illness sexual adjustment. If sexual expression and performance had been an important part of the pre-illness relationship they continue to play an important role; if they were relatively non-existent they usually remain so.[19] [20]

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Salvage of the Diabetic Foot: Surgical Considerations

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Abstract—There are a number of cofactors in the progression of peripheral vascular disease, including diabetes, hypertension and hyperlipidemia. Perhaps the most important one in our clinical experience which is now over 1,200 permanent popliteal reconstructions and close to 1,000 new patients a year in the institution as a whole is the effect of cigarette smoking. When a patient has diabetes and vascular disease with good doctoring he can make it; but if he's a smoker, he's in trouble. We insist that all of our patients embark on a no-smoking program following any type of arterial bypass grafting and most of them do. They've got to maintain their lean weight and get involved in a regular exercise program and this is possible even in the most infirm individual by simply making the exercise program fit his limitations. Such exercise programs increase blood flow to the lower extremity, open up collaterals, and I believe in the long term, maintain the patency of our bypass grafts. Fourthly, and most important, continued regular fastidious foot care with or without bypass grafting, with or without surgery, is essential if we are to maintain and salvage the diabetic foot.

A panel on peripheral vascular disease convened by the National Heart and Lung Institute in February of 1972, found that one-half of all hospital beds in the United States were occupied by patients with diabetic foot complications. It is also well known that 80% of the amputations in both diabetics and non-diabetics result from neglect and improper care resulting in infection rather than ischemia per se. Some of these complications can be avoided. The importance of a team approach by the surgeon, social worker and visiting nurse must be emphasized in the day to day care of the patient with a diabetic foot problem. This is particularly true of the elderly patient with coexisting cardiac, renal and visual difficulties.

The surgeon has many responsibilities in the salvage of the diabetic foot. He should be prepared to perform a prompt and adequate drainage in the neuropathic foot. He should be able to select the proper patients for local amputation with a reasonable assurance of primary healing. Rarely is sympathectomy justified in the diabetic patient. They have already been autosympathectomized for the most part. The vascular surgeon primarily adds to the care of the diabetic patient by the performance of bypass surgery, oftentimes followed by local amputation. Arterial obliterative disease exists at the aortoiliac segment at the femoral popliteal segment and at the tibial level. The patterns of disease involving these sites are well established. How does the diabetic vascular disease differ from the standard atherosclerotic American type of disease? As pointed out before, it starts ten to fifteen years earlier. The disease has a very typical centripetal progression; tibial vessels involved earlier than the femoral popliteal area. Aorto-iliac involvement is rare. In my experience, the diabetic vascular disease is often times very slowly progressive with extensive collaterals developing and I have seen more than a few patients with complete block of the aorta, common iliac, femoral, popliteal and have early involvement of tibial vessels. Such patients have a normal inflow at rest in many instances and exist on a lumbar - hypogastric - profunda - geniculate - tibial collateral circulation. Such patients will do well in many instances except during claudication which they can learn to live with until infection develops or until one of the primary collateral branches becomes involved, most commonly the profunda femoris in the groin interrupting this chain of collateral circulation. Then the patient is in trouble.

Assessment of Diabetic Foot for Revascularization

The indications for surgical study in the diabetic patient with absent pedal pulses include the following: 1) suspected foot sepsis with current digital lesion; 2) failure to heal an ischemic ulcer; and 3) ischemic rest pain and progressive disabling claudication. The surgical assessment includes 1) a routine history and physical examination; 2) assessment of pulses; 3) the location of bruits and particularly important the 4) local examination. I'm talking about the ingrown toenail, the interdigital ulcer, the plantar wart, callous, bunion and particularly the heel lesion, the heel fissure from which a lot of mischief starts. If a patient is in a little bit of trouble, we don't ship him into the hospital and do an arteriogram because there are better ways,

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easier ways, and more economical ways and more accurate ways to do it. We submit our patient to our vascular laboratory and we would then do some noninvasive studies before selecting the patient for bypass grafting or amputation. These include measurement of segmental limb pressures and segmental pulse volume recordings which is similar to oscillometry in many ways; angiography with direct pressure measurements is performed in selected patients. We believe that limb pressures and pulse volume recordings provide us with a hemodynamic assessment of the patient's limb whereas the angiogram provides us with structural information from which the surgeon really has to use in order to apply his craft properly. Selection of the patient for surgery includes the location of the obstruction, aorto-iliac disease, femoral popliteal occlusive disease, the degree of involvement of the inflow tract, the outflow tract, the general condition of the patient, particularly in regards to coexisting cardiovascular disease, and a genuine realistic look at the overall objectives. Generally speaking we believe that revascularization, if it can be carried out with low mortality and low morbidity in experienced hands with the hope of long-term patency, is preferable to a major amputation even in the fragile diabetic patient.

In our hands at the Massachusetts General Hospital, the major amputations still are more traumatic and carry a higher mortality than a well executed bypass graft, particularly in the femoral popliteal region. Now, let's look at how segmental limb pressures help the surgeon select a patient for arterial reconstruction. The Doppler ultrasonic velocity detector is used to detect the presence of bloodflow by audibly or graphically depicting the frequency shifts in the standard ultrasound of energy wave which it generates. The wave is introduced transcutaneously into the tissue and focused in the general anatomical location of an artery. If the vessel is patent as it is in most instances, a signal can be obtained. The calf, thigh and ankle pressure should be equal to the systemic pressure unless there is a hemodynamically significant lesion in between. About 40% of patients with diabetes who present with gangrene of the lower extremities have palpable popliteal pulses, and as such are not candidates for any kind of permanent popliteal reconstruction. This elderly thin lady presented with a palpable popliteal pulse. She wasn't turned down for surgery. She was not subjected to immediately dangerous angiography but had determination of segmental limb pressures. Her systemic pressure was 150, thigh measurement was 155. At the calf, however, it was 95, and it was 65 at the ankle. The point is that there was a pressure gradient and a significant lesion was identified on an angiogram. This patient did have a femoral popliteal graft and the postoperative studies showed systemic pressure in the calf although she continued to have distal disease; her ankle pressure is now in the region of 100. So this is one demonstration of how a noninvasive vascular laboratory test can help your patient by pointing out a hemodynamically significant obstruction.

The pulse volume recording which is an expression of pulse volume changes in the extremity give us a measure of collateral flow. This is a standard vascular laboratory study in our vascular laboratory. A machine which combines both the Doppler and the pulse volume recorded is available (information about this can be obtained from Dr. Raines at the Vascular Laboratory at the Massachusetts General Hospital).

The next move, of course, if we find we have a hemodynamically significant lesion is to do a complete arterial study of the lower extremity, and this means an aortogram and femoral arteriogram in most instances. The majority of our patients have obstructed outflow tracts. In many instances, we have to graft to tibial vessels. This is only satisfactory if the tibial or perineal vessel is completely patent all the way down to the ankle including the tarsal arch. This is not classic for the diabetic patient who often times has extensive disease at the level of the tarsal arch. So the majority of our diabetic patients are not candidates for a femoral tibial graft but rather a graft to an isolated popliteal segment is preferable. I've been terribly impressed over the years how well these patients do.

Surgical Treatment

When the aorta or iliac vessels are involved and there are no palpable pulses in the groins, revascularization is commonly done in the diabetic by resecting the distal aorta and insertion of an aorto profunda bifurcation graft. We reserve an aorto-iliac endarterectomy for segmental disease, and we have never seen a well established diabetic with isolated aorto-iliac occlusive disease and open distal vessels; almost all have involvement of the femoral popliteal and/or tibial vessels. So that new construction at this level should be carried out well down under the profunda femoris artery. In most instances, a simple, aorto-femoral graft would be sufficient to revascularize the diabetic who has no femoral pulses, and more than adequate to salvage the limb in most instances. In patients with good femoral pulses, but none below, salvage of the foot can be carried out by femoral popliteal reconstruction with a reversed saphenous vein bypass graft from the common femoral artery down to the distal popliteal. About 80% of individuals will have an adequate vein, that is more than 4 millimeters in diameter to bypass this entire segment, and we prefer in most instances to bypass the entire diseased segment putting the distal anastomosis in first below the knee in about 80% of patients. In our experience, this reversed saphenous vein bypass graft is a procedure of choice and in only 20% of instances need we resort to a second-rate procedure. In our experience, this sort of a bypass is, by all means, preferable in terms of morbidity and mortality to a major amputation even in a most fragile diabetic. There are two types of arterial reconstruction in the femoral popliteal region—the good kind and the not so good kind. The good kind are the autologous saphenous vein grafts with patency rates of two years of 87%, at five years of 76%. Now there is absolutely no difference in our diabetic patients whatsoever as far as patency rates in the vein grafts. There is a considerable difference, however, in the mortality rate in the first twenty-four months following popliteal grafts for gangrene. Approximately 20% of our diabetic patients die of coexisting disease in this early followup period. Still this does not mean that the permanent popliteal graft was unnecessary because in most instances it prevented a major amputation. A composite Dacron graft, bovine graft, bovine heterograft, endarterectomy and vein grafts, endarterectomy and the DeBakey type of operations don't work out well in the diabetic patient. There is, however, a salvage rate of about 40% for two years and patency rates in our hands at five years is about 22%. Now that doesn't mean that these second rate operations are necessarily contraindicated because many diabetics will heal up their lesions even though they do occlude later on. These patients if they are followed carefully and maintain their proper foot care, can maintain their limb salvage. A femoropopliteal graft may protect the patient from a high limb amputation. A transmetatarsal amputation makes a very nice functional foot. The group at the Joslin Clinic had twenty-three patients, who had only transmetatarsal amputations following their vein grafts. I think that this lesser amputation was possible only because of a well constructed femoropopliteal procedure.

Precordial Catch Syndrome

Miller and Texidor have described as a syndrome recurrent attacks of left-sided anterior chest pain that was observed in 10 healthy young persons under the age of 35 years. There was no predominance in either sex.

The onset of the pain was sudden and severe, and the discomfort lasted from one half to three minutes. It was located near or above the cardiac apex and did not radiate. There was no tenderness over the precordium, and no physical abnormalities of the lungs or chest wall could be demonstrated. The attacks occurred at rest or during mild activity, and the onset was frequently related to a slouched or bent-over posture. The etiology of this syndrome is not known. Relief of pain was sometimes obtained by having the patient assume an erect posture or take a deep breath.—A. Miller, and T. Texidor: *J.A.M.A.* 159:1364, 1955.

Role of the Podiatrist in the Management of Diabetic Foot Problems

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Because of the fine effort of the medical profession in the use of insulin, proper diet and many oral hypoglycemic agents, the regulation of carbohydrate metabolism of the patient afflicted with diabetes mellitus is being placed under control, and therefore these patients have acquired an increased life span so that deaths attributed to coma or starvation are becoming increasingly rare.

However, because of this longevity many more complications of the disease are now becoming apparent. Coronary artery disease is often seen, with seven of ten diabetics dying of heart disease. It is the third leading cause of blindness, kidney involvement is not rare, and of course the foot has become increasingly susceptible to problems.

Most diabetic foot lesions result from diabetic neuropathy and angiopathy. Changes in the vascular system consist of large vessel involvement, macroangiopathy, and small vessel pathology involving the small arteries, arterioles and microvascular lesions of thickened capillary basement membranes. It is this thickened basement membrane that is so characteristic of diabetic vascular disease. It is these vascular changes in the diabetic's foot which make him vulnerable to trauma, infection and poor healing. It should be noted that vascular changes in diabetics are usually bilateral in contrast to nondiabetics which are usually unilateral. Also another major difference is the extensive disease of small vessels and microangiopathy of capillaries in the diabetic patient. The significance of the basement membrane thickening is unknown. Some contend that the thickness of the basement membrane acts as a barrier preventing intravascular nutriments into interstitial space while others contend the opposite, that there is an abnormal increased permeability of the capillary wall to ions and albumin. The larger vessels most frequently involved are the tibials and popliteals.

Some of the symptoms of vascular disease in the diabetic foot and leg are intermittent claudication, rest pain, absent pedal pulses, although palpable pedal pulses can be present in the face of microangiopathy. Other signs are atrophic skin changes, frequent infections and ulcerations, and of course gangrene. One of the reasons for the frequent number of cases of gangrene in the diabetic patient is the widespread disease in small vessels where very little collateral circulation can occur. The pain of intermittent claudication is aching in quality, usually occurs in the calf muscles, after exercise, and usually ceases within a couple of minutes after the person stops walking. The timing of exercise followed by pain and subsidence of pain on rest is characteristic of pain due to obstruction of circulation. This sequence also occurs in angina pectoris. The relation of pain to exercise is easy to understand. When contracting, muscles require a larger supply of blood oxygen and other nutrients than when at rest. When the patient begins to walk the sclerotic or blocked artery cannot allow a sufficient blood supply to meet the extra needs of muscles resulting in anoxic pain. Generally any blockage is above the level of pain, thus a patient with an obstructed aorta or iliac vessels will experience pain in the buttocks or hips and pain in the calf may be due to blockage of the femoral-popliteal vessels.

The second frequent reason discussed in causing diabetic foot disorders is diabetic neuropathy. Again there is no conclusive etiology for the neuropathy but the most frequently cited reasons are hyperglycemia, insulin insufficiency alone, vascular insufficiency of the vasa nervorum and metabolic abnormality of the nerves or any combination of the previous mentioned. Diabetic neuropathy usually involves the lower extremity and usually is bilateral. The sensory involvement can either be of pain and paresthesia or conversely a decreased sensation to pain and temperature. The decreased sensation to pain accounts for the reason the diabetic develops painless neglected lesions which become large, infected and even gangrenous before being detected. The pain associated with diabetic neuropathy is frequently relieved with mild walking in contrast to pain due to vascular insufficiency, which usually increases on walking.

Charcot joint is another common result of diabetic neuropathy as destruction of the joint becomes the end result of constant trauma, painless due to the neuropathy. This psuedo tabetic foot often reveals plantar ulcers without true infection. Pedal pulses are usually good. Neurotrophic ulcers usually have a much better prognosis than vascular ulcers which often time leads to amputation.

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Because foot lesions are common in diabetes, the podiatrist is often the first doctor to examine the diabetic patient, and since half of the four million people afflicted with the disease are not aware of it, one must be very attentive to a good foot examination on all patients that present themselves to our office.

Each new patient or any long absent one is questioned as to whether he has diabetes or has any family history of such. Pedal pulses are taken on all patients and a superficial neurologic examination is done bearing in mind that of all neuropathic manifestations, the loss of the ankle jerk is often the earliest sign of diabetic neuropathy. All patients are questioned as to the name of their medical doctor. Any patient who presents himself with infections underlying a plantar or dorsal excrescence, or who might display a paronychia single or multiple, with or without palpable pedal pulses, comes under suspicion of having an underlying metabolic problem rather than just a local irritation. Patients with uncontaminated ulcerations, painless inverted toe nails, thickened toe nails with pressure ulcerations, mycotic infections with secondary bacterial infections should also come under close observation. If it is confirmed the patient has diabetes mellitus, either from consultation or referral to the medical doctor, the patient is treated with extreme caution.

Each patient is given the customary rule guide on the proper care of the diabetic foot, rules such as:

1. Wash feet daily and dry carefully.
2. Examine feet daily for scratches, blisters, and cuts.
3. Do not attempt to use chemicals or knives for the removal of corns or callouses.
4. Cut toe nails straight across and not too short.
5. Avoid walking barefoot.
6. Inspect inside of shoes for foreign objects or pressure points and wear proper fitting shoes.
7. Avoid wearing garters.
8. Avoid extremes of temperature.
9. Avoid wearing mended stockings and naturally change stockings daily.
10. See your physician and podiatrist regularly.

Although these rules may be oversimplified or repititious, they cannot be overstressed because it is the prevention of foot problems that is so very essential in the prognosis of the diabetic foot.

Diabetic patients who appear in the podiatrist's office with non-complicating excrescences are treated conservatively and with caution with an attempt to avoid unnecessary trauma. Those who present themselves with small localized infections without accompanying cellulitis, under reasonably good systemic care and with adequate blood supply usually respond quite readily to antiseptic debridement, relief of pressure, antiseptic foot soaks, and/or proteolytic enzyme ointment.

Patients with plantar ulcerations with established infection or incipient gangrene are the patients who present the everlasting challenge. If these patients have not been referred by their physician, he is immediately contacted, made aware of the condition and referred for systemic diabetic evaluation. These conditions respond slowly and poorly normally and in an uncontrolled diabetic it is extremely difficult to bring about a satisfactory result. Once good medical relations have been established the local condition is treated. Superficial callous, which usually covers the ulceration, is removed, the wound debrided and early drainage is established. Immobilization and elevation of the extremity is desired. It is essential to obtain material for culture and antimicrobial sensitivity testing and moderate or high dosage antibiotic therapy should be initiated. Some antibiotics that are used immediately are cephalothin 1 to 2 gm every 6 hours or cloxacillin 1 to 2 gm every 6 hours plus, kanamycin 0.5 gm every 12 hours.

Most cases of osteomyelitis within the foot of the diabetic patient begin as chronic perforating ulcers. Mixed infections are common, staphlococci are usually found in association with group B-beta-hemolytic streptococci. If an ulcer is neglected or improperly cared for, bacterial invasion may progress at the base of the lesion by spreading along facial planes or by penetrating fascia and soft tissues to reach the periosteum. Once frank osteomyelitis has resulted from such a progressive process in a limb with vascular insufficiency, the probability of amputation is high. This is important to bear in mind because statistics have revealed that following amputation of one leg, the loss of the second leg usually occurs within three years in 1/3 of the patients, and that 2/3 of the diabetic patients who have an amputation will not be alive in five years.

Medicaments used to hasten healing of plantar perforating ulcers vary, depending on many factors. At times moist compresses saturated with isotonic saline solutions are helpful, and often times Burow's Solution compresses are utilized. Frequently a proteolytic enzyme ointment can be used to debride the wound of any necrotic tissue that is not able to be removed by sharp dissection. Healing sometimes can be hastened by one of the aniline dyes such as gentian violet solution. For those patients who are unable to be placed at bed rest, soft balanced foot appliances can be used to alleviate pressure on weight-bearing ulcers. Moulded shoes can also be used as balance therapy.

Summarizing, one must be aware that the incidence of diabetes is increasing, and the diabetic's life span has also increased so that he is now living long enough to develop the complications of the disease. Since these complications so often involve the foot, the podiatrist plays an important role in detection and treatment of foot infections and ulcerations. The podiatrist is becoming an important member of the health team because other practitioners do not have time to devote to the management of these foot problems.

Dr. Frederick Wood Jones, Professor of Anatomy, University of Manchester (1943), once said:

"Man's foot is all his own. It is unlike any other foot. It is the most distinctly human part of the whole of his anatomical make-up. It is a human specialization and, whether he be proud of it or not, it is his hallmark and so long as Man has been Man and so long as he remains Man it is by his feet that he will be known from all other members of the animal kingdom. He may speak slightingly of feet of clay and imagine his form to be divine with perhaps the exception of his feet, but with all his conceit he must not ever forget that it is, in fact, his feet that confer on him his only real distinction and provide his only valid claim to human status."

The podiatrist is attempting to do much to help the diabetic maintain this human status.

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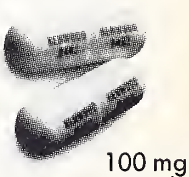

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Early Ambulation After Below-Knee Amputation

Morris D. Kerstein, M.D. and Frederick Dugdale, M.D.

ABSTRACT—Rehabilitation must dominate patient care from the outset, not following amputation. The application of the rigid dressing followed in ten days to two weeks by an early prosthetic fitting utilizing the principles of patellar-tendon-bearing have been demonstrated.

The early application of a temporary or interim prosthesis in patients with adequate systemic competence will speed the period towards full rehabilitation with a permanent prosthesis. Beginning with the work of Berlemont[2] and Weiss[1] in the 1960's the practice of immediate and early postsurgical fitting of prostheses revealed the advantages of more rapid healing of the amputation site, earlier stump maturation, decreased pain and psychological comfort. The neurological implications of a provisional prosthesis provide an emotional and physical stability. Partial to full weight bearing, preservation of balance, kinesthetic senses and gait are maintained.

This manuscript is primarily concerned with presenting a plaster-cast type patellar-tendon-bearing temporary prosthesis. Following below-knee amputation a rigid dressing may or may not be applied (the former is the more desirable). At that time when the stump incision is clean, healed and the sutures are removed (10-14 days) the temporary prosthesis is applied.

Technique

At the time of suture removal in a well healed below-knee stump, the situation is correct for the plaster-cast type easily removable patellar-tendon-bearing, temporary prosthesis (Figure 1). A stockinet is applied to the stump over a rolled piece of cardboard. Three felt pads are applied to reliefs (Figure 2 and 3). Regular plaster (three inch) is rolled about the stump with pressure placed below the patella and in the inferior popliteal area (Figure 4—A&B). A "Y" strap is incorporated in the third roll of plaster (Figure 5—A&B). The strap is attached to a waist belt. The pylon or foot-ankle assembly is attached 24 hours later (Figure 6). The plaster mold may be removed nightly and as the stump shrinks more

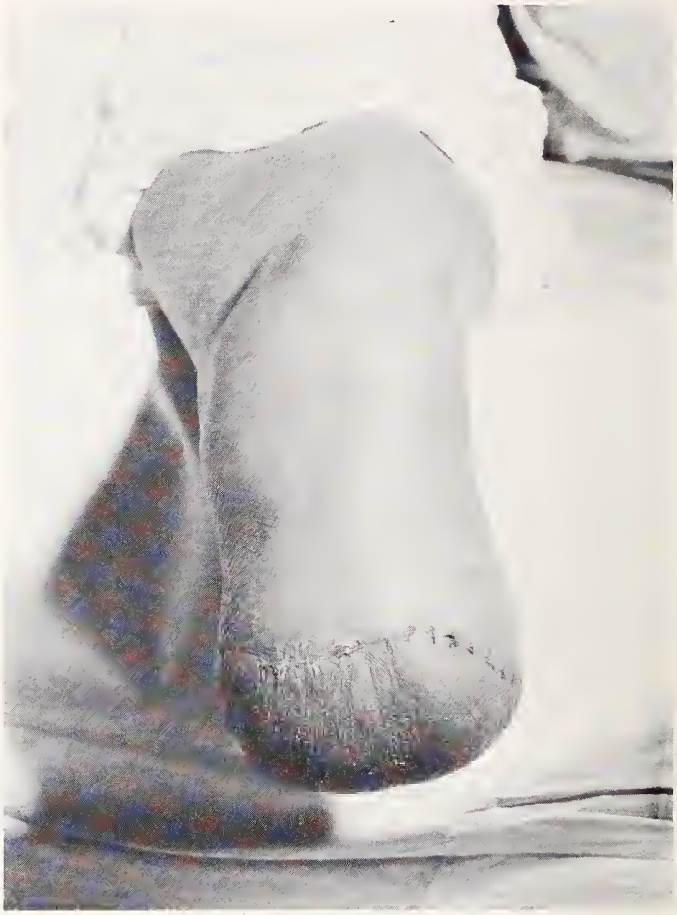
Figure 1

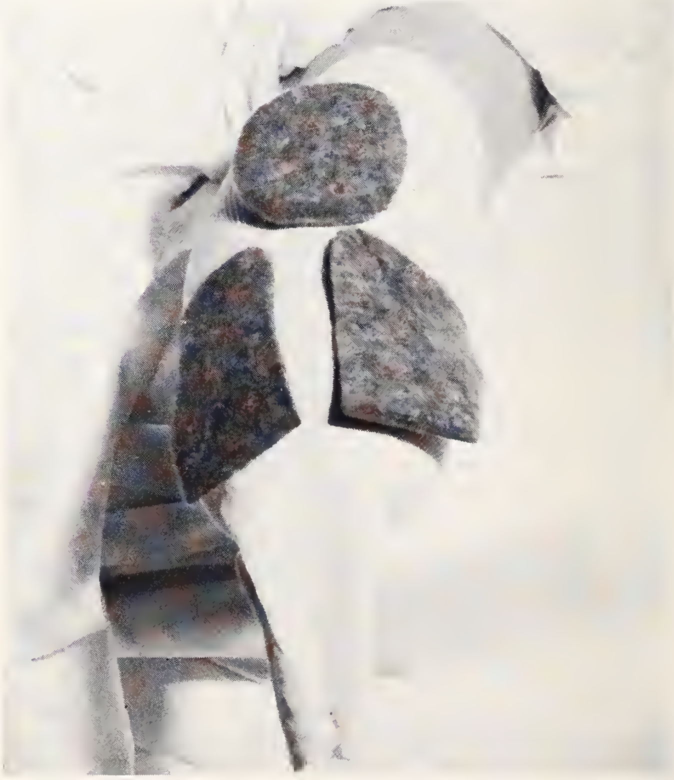
Figure 2

DR. MORRIS D. KERSTEIN, Assistant Professor of Surgery, Yale University School of Medicine; Staff Surgeon, V.A. Hospital, West Haven; Staff Surgeon, Yale-New Haven Hospital.

DR. FREDERICK DUGDALE, Chief, Department of Physical Medicine and Rehabilitation, V.A. Hospital, West Haven.

stockinet may be added. It is usually two to three months before a permanent prosthesis is available, yet, the patient may be up and out of the hospital within two to three weeks.

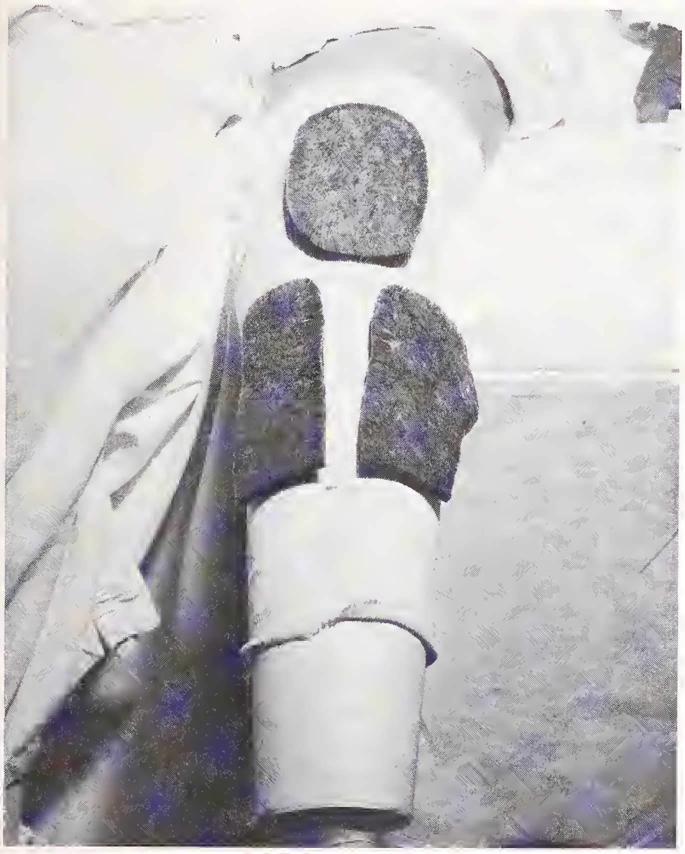

Figure 3

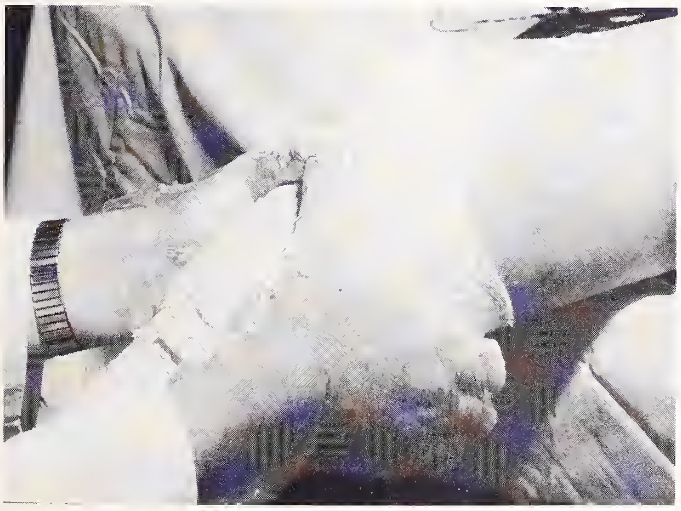

Figure 4A

Discussion

When acute or chronic arterial insufficiency reaches a stage where viability of tissue is not to be maintained, amputation will be a requirement. The remarkable advances of reconstructive peripheral vascular surgery during the previous two decades is a significant chapter in the history of medicine. Yet, despite these advances it is suggested that amputations for ischemia are increasing absolutely,

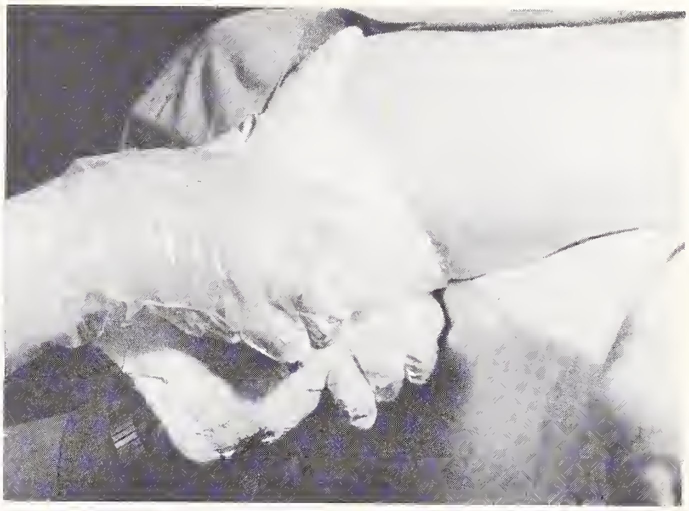

Figure 4B

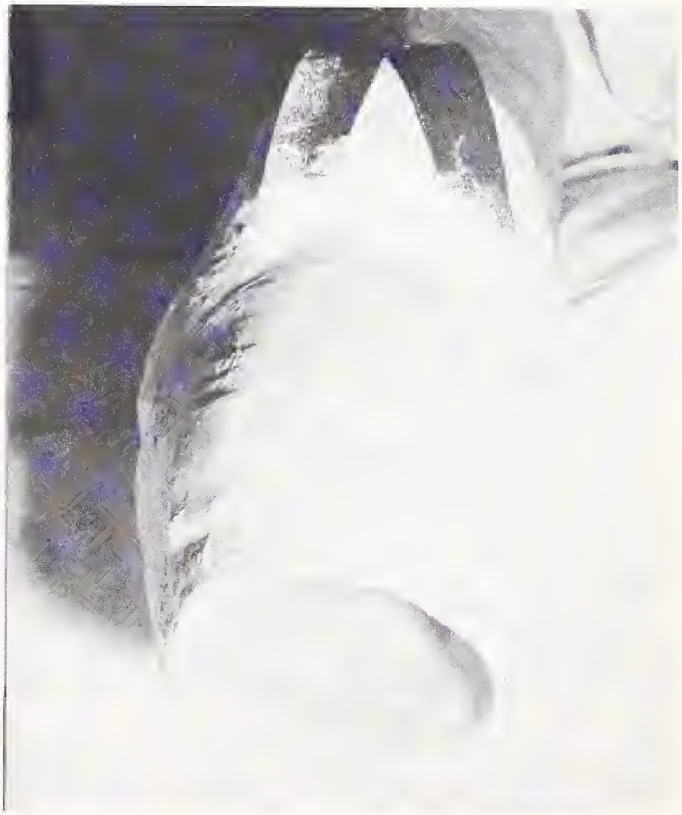

Figure 5A

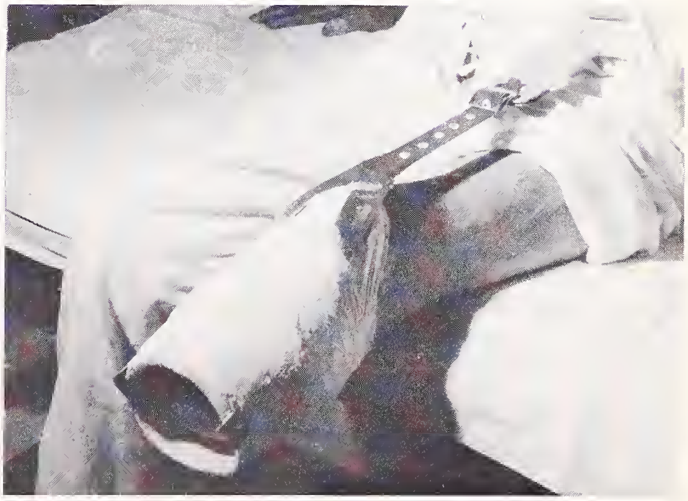

Figure 5B

and in relation to population growth throughout the western world.[6] Patients who are not "successes" with reconstructive vascular surgery are entitled to comparable medical and surgical consideration, team effort and high-level attempts at rehabilitation management. Amputation is not the end of a number of surgical enterprises but another step towards rehabilitation, towards a full participation in community life.

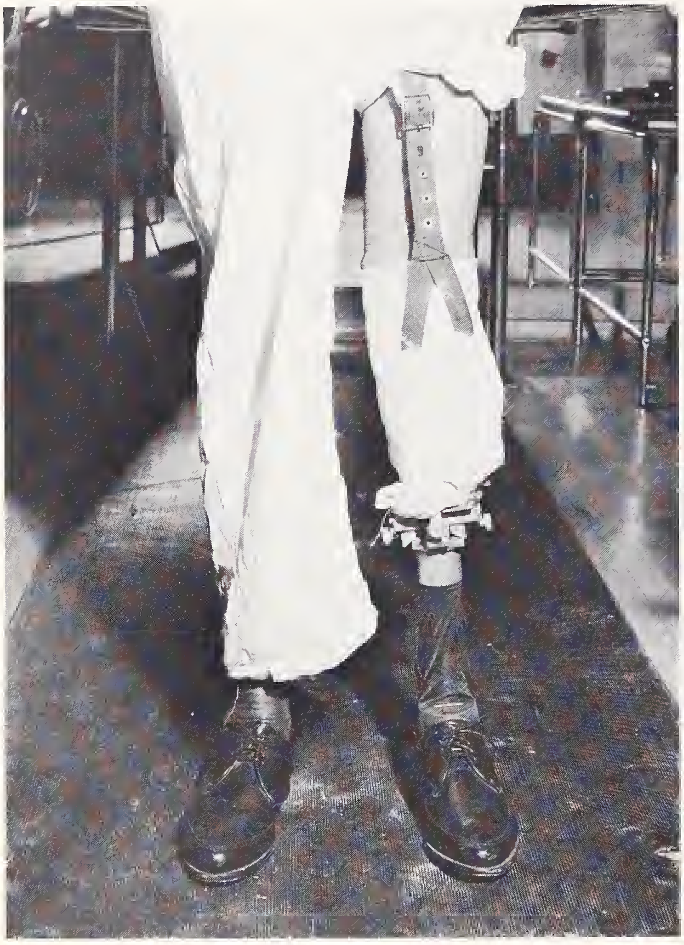

Figure 6

Since the surgeon should consider rehabilitation as the primary goal, not limb salvage, due consideration must be given to the individual who can only tolerate a limited number of anesthesias. The surgeon must evaluate "the gamble" on the loss of a reconstructed extremity and the conversion of a below-knee amputation to above-knee. There is no single test or combination that will absolutely demonstrate the lowest effective amputation level. Below-knee amputations have successfully been done with arteriograms showing complete block of the superficial femoral artery and poor to no 'run-off.' The salvage of the knee joint remarkably enhances rehabilitation.

The below-knee amputation and the utilization of a long posterior flap is well described.[5] An immediate postsurgical rigid dressing is then applied. The rigid dressing is a mildly compressive, total contact plaster[4] or inflatable air splint[3] applied to the stump immediately following surgery for the purpose of pain, elevated temperature or elevated white count the rigid dressing must be immediately removed and the wound inspected.

In the immediate postoperative period (second or third day) the patient should be seen in the department of physical medicine and rehabilitation. Having been seen prior to surgery, there will be no delays. The patient is prevented the loss of kinesthetic sense with the use of parallel bars and the tilt table. Shortly after the sutures are removed on the tenth to fourteenth day—the patient is given the temporary plaster type patellar-tendon-bearing prosthesis, allowing for continuing rehabilitation.

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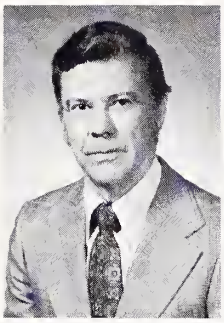
The President's Page



Does anyone here still speak for patients? Recent legislation suggests that if we do, no one is listening. The planning bill P.L. 93-641 is notable for the token representation afforded the profession. When we do speak our voices seem faint and muted, lacking clarity and consensus. Our proposals are the suspect because they often seem peculiarly slanted to enhance and protect the financial well-being of the profession or the institutions we represent rather than the people we are supposed to serve. Our policy statements and position papers are belittled or ignored by our legislators. The political history of the Republican Party in South Dakota during the 1890's would elicit more interest.

There is, however, no shortage of patient spokesmen. Not only other health care professionals but representatives of many other trades and disciplines, all vying for the rostrum in order to depict the health care scene in terms of unrelieved "doom and gloom." This, together with the usual crisis rhetoric, can only impair and impede rational debate in the area. As a field in which one can have strong convictions with a minimum of knowledge and experience, medicine is rivaled only by education.

Actually this expression of public worry is appropriate and the right of public discussion should not be debatable. Medicine is not some disinterested science to be discussed solely by scholars. Medicine is a product of our own human weaknesses and our ultimate mortality and cannot be divorced from the main stream of life. It is a service requested by and rendered to the injured, the ill, and the might-be ill. Without patients the profession would have no justification for its being. The evolution of the physician's role can be viewed simply by how we have responded to and provided for our patient's needs. Accepting these premises, the present agitation for quality medical care, easily accessible and provided at reasonable cost, is understandable.

The doctor of medicine role is changing because of society's perception of its own need. We are being asked to change from a vested interest in disease to acceptance of a role in the total social responsibility for our patients. The new students entering medical school have accurately interpreted this concept. This, together with their own values, suggests a new image and purpose for the future.

We must regain our spokesman role. So much of the material being published and debated reflects the wishes, hopes, and dreams of the authors rather than the true state of affairs. So many of the proposals carry the nominal air of solving problems but actually conceal the promise of wrecking the whole fabric of medical care. The government continues to cut back on benefits and renege on promises to the elderly. Our industrialized hospitals, while rendering task-centered rather than patient-centered care, continue to listen to patients' complaints filtered through the twin tin horns of cost control and regulation.

Physicians cannot, however, expect to maintain the same private and privileged relationships with our patients we enjoyed in the past. We, like the press, have become a semi-public institution and must expect the same kind of scrutiny all other semi-public institutions receive. Also, like the press, while we both should be free, it is only by being responsible and responsive that our freedom can be assured.

It is not often that circumstances permit the synthesis of a humanistic concept with a relevant and rational end product. *Pro bono publico* as a motto and guiding principle for present and future policies offers just such an opportunity.

GUY W. VAN SYCKLE, M.D.
President

Reflections From The Dean's Office

Robert U. Massey, M.D.

The past 50 years of medical education have seen unparalleled changes in medical science and medical practice, and yet, seen from another perspective, these changes may be relatively small because they are built upon an older and more enduring framework.

Those 50 years in medical education have all been part of the post-Flexner era, and the essential principles of that Carnegie Foundation report of 1910 have had remarkable durability. Nor has the organization of medical care in this nation undergone radical alteration. Health services still display most of the outward forms of the twenties and thirties. Like the outward forms of government, the symbols, structures, and procedures give a sense of continuity and permanence, while orderly and disorderly change takes place beneath the surface, unclear to us because we are standing too close.

Vernon W. Lippard, dean emeritus of Yale School of Medicine, has recently written a book entitled *A Half Century of American Medical Education.* For those of us who have lived through most or all of those 50 years, Dr. Lippard's fine historical review helps put our recollections in order. For those who are fearlessly setting the course for the next 50 years, an overview of the recent past could prove salutary.

It is now commonplace to observe that between the twenties and the seventies the world changed more than during the previous several hundred years. That statement should not be accepted uncritically, because there are many things which have not changed even within our own anthropocentric world, never mind the world of nature of which 50 years is nothing. Some technological and scientific changes have been exponential, as have been population growth and energy utilization. The forms and processes of government, the patterns of human relations and human behavior have been slower to change and would be recognized by our grandfathers.

There is no doubt that the organization of medical care and health services is about to be modified by a spate of state and federal legislation resulting from that insistent desire for power, need to curry votes, and to respond to special interests. and the occasional statesmanship and good will which characterize the political process. In all of this, there is danger that legislative events will get out of hand and planning and goals may become uncoupled.

There are important implications for medical education. Dr. Lippard sees danger in some of the recent trends in medical school programs: "The core curriculum introduced in the past few years is resulting in diminished emphasis on the basic sciences, and in an effort to produce more physicians faster, the medical course is being abbreviated. These changes are, in my estimation, misguided . . . The curricula of some new schools look very much like the programs for training physician's assistants."[1]

Recently a leader in health planning in this State characterized the National Health Planning and Resources Development Act of 1974 (P.L. 93-641) as the "most important piece of health legislation in this century." There are ten national health priorities in that law. Fundamental research in human biology and investigation into the nature of disease are not among them.

Perhaps this should not worry us; it could be argued that the authors of the law did not intend to deprecate research by failing to mention it, that they were in this instance concerned with other matters. However, the voices of antiscientism and antiintellectualism are too insistent to believe that the lawmakers are deaf to them. Shryock in *Medicine in America* devotes an entire chapter to *American Indifference to Basic Science during the Nineteenth Century.* He reminds us that Tocqueville, writing in 1835, "believed that the combination of democracy and of economic opportunity inevitably led to a neglect of theoretical science and to a cultivation of technology."[2]

There is a danger that medical education could be induced to follow the fashions, and that American medical colleges, the best in the world, might become government agencies designed to provide the nation with workers for the health trades, skilled but uncritical technicians caught for a generation or so in the mid-twentieth century.

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DR. ROBERT U. MASSEY, Dean and Professor of Medicine, University of Connecticut, School of Medicine, Farmington.

Editorials

Malpractice Panel Reviews—A Suggestion

One of the solutions being considered in the current malpractice problem is education of physicians about it. In the formulation of our state Aetna plan, its staff of physicians, lawyers, and case investigators has devoted considerable effort to this— making educational video tapes and visits to hospital and medical groups throughout the state. At a recent review of the program by the state society malpractice committee, however, it was concluded that the program had not accomplished its goals. The fault, if any, does not necessarily lie with Aetna's program; it may more likely be the subject, and its students the doctors. We must ask: "Can malpractice, especially as a legal concept, be taught to physicians, whether they be in practice, during their residencies, in full-time clinical teaching, or on faculty?"

During its review, the committee found one method whose value from the beginning seemed to create a positive reaction—satisfaction educationally from serving on review panels by the participants. Unfortunately, at most 120 physicians of the 3,140 or so members in our program can participate.

But if the educational value from them is as valuable as most participants maintain, can and should the technique be transferred into hospitals where about 80% of malpractice suits originate (especially since most hospitals in the state are now covered in malpractice by Aetna) and where malpractice incidents involving hospitals may increase even more steeply than those now involving individual physicians. Let's describe briefly how one of these committees functions, and then ask the necessary questions.

When the program was adopted, the state was divided into four review panels, each with about 18 physicians representative of a broad spectrum of community and specialty. Few of the total number of cases need be presented to a committee; it exists mainly for problem cases—for Aetna, its lawyers, and any physician in the program. Cases of possible malpractice can usually be settled by Aetna without going to a review committee. Physicians serve free.

Questionable or problem cases, after a thorough review by Aetna investigators, are assigned to a lawyer chosen by Aetna for competence and experience in malpractice. If he thinks there is need for medical expertise, he asks the chairman to appoint a member in the specialty involved as case manager. He is given the entire file to make a thorough medical review. He may question the physician being sued, Aetna's staff, the lawyer, other specialists, or anyone who may be helpful or necessary to present the case fully and fairly. Proceedings of committees are confidential and privileged.

When the case manager decides he is ready to present the case, the chairman sets the date for the committee, including the lawyer, Aetna's staff, and the defendant, who, in fact, is required to appear before the committee for questioning.

The defendant's lawyer calls the meeting to order, briefly explaining the legal complaint. Next, the case manager gives the story in depth. He is then subjected to probing questions about the medical management of the case. After this, the defendant is invited in to answer questions and to present his side. After he leaves, the committee again reviews the case before voting.

In the voting on possible professional negligence, the law setting the standards of medical practice is read to the committee by the lawyer. The standards are not those of the best or worst in his specialty; nor are they necessarily those of the committee nor of the case manager. The standard of practice is determined by what other reputable practitioners in the community, or in similar communities, would or would not do in the care of similar cases. If he holds himself out as a specialist, he must meet the standards of his fellow specialists. Where the standards, years ago, may have been those of the community, they have broadened so that in Connecticut the standards of medical practice are generally held to be those of the entire state.

With this standard in mind, the members vote by secret ballot. The panel makes one of the following recommendations:

A. A settlement (malpractice) because of deviation from the standards enumerated.

B. A compromise settlement because the case is clearly not one of malpractice but may be difficult to defend.

C. Defend, but the more the voting should deviate from unanimity, the more a settlement may be indicated.

The recommendation is made to the lawyer. He makes the final decision, along with Aetna, because the ultimate determination is legal. The panel, however, has made a thorough, in-depth discussion of the medical management of the case. The nearest analogy, and it is quite apt, is to the Cabot cases as reported in the *New England Journal of Medicine*.

Now comes the question, should the procedures of our district claim review panels, used in our state malpractice program, be transferred to hospitals as an *educational* device, at least on a trial basis?

Let me conclude with an editorial yes, from one who has been with the program from the beginning, and has more than the usual physician's interest in the law. And let me state a few of the principal factors involved, if only to generate discussion.

(1) Education of physicians about malpractice is beneficial and worth trying, provided suitable methods can be found.

(2) Of the methods used, the screening or review panel seems to be most satisfactory to those who have participated, especially in the light of almost total rejection of other traditional methods of teaching.

(3) Most hospital malpractice incidents originate in hospitals (about 80%). Certain critical events such as unexpected death, paralysis, brain damage, amputation, unexpected blindness, and unsuccessful new techniques lend themselves to the allegations of malpractice. With the present liability of hospitals to malpractice, the incidents of malpractice suits probably will increase even more steeply than the present rise in physician suits.

(4) The fact that most malpractice coverage for physicians and hospitals in the state is covered by Aetna is an advantage for such a program; and the Aetna-CSMS program apparently has been so successful that Aetna has sold it to about eight other states.

Even more important, however, is that the use of such panels or hospital malpractice committees will impress upon hospital medical staffs that malpractice essentially represents a breakdown in medical management of a case in that it does not adhere to that "degree of skill and care commonly possessed and exercised by other reputable physicians in the locality." Many hospital medical staffs will have to be frank and honest and look within themselves: that though the present "crisis" in malpractice is not necessarily the result of poor medicine, there has been no real review of malpractice cases in their hospitals; that such cases have been treated with studied silence; that there is no positive program in hospitals to review incidents even for their educational value.

Every hospital should have a malpractice committee. It should meet regularly, monthly at least. Participation and attendance should be mandatory. Malpractice is no longer a problem for the profession; it involves society to the extent that the profession has gone to legislatures for relief. In return, the profession must demonstrate to society that it is doing something, actively and visibly, about the problem. It has not done so up to date. At its last annual meeting, our Society's House of Delegates rejected the idea of continuing medical education as obligatory and as a condition of membership in the State Society. It may be correct, logically and reasonably, but, from the public's viewpoint, it merely represents a negative approach to what they consider or have been led to believe is a necessity.

These hospital committees should in the beginning be as nearly like those of state panel committees. As time goes on, they may modify and change them. To set them up, they can be assisted by Aetna and by physicians who are now serving on these panels. Such committees certainly should review cases of malpractice that occur in their hospitals; for educational purposes, Aetna can furnish anonymous teaching cases.

Can they be conducted without a lawyer's being present? They can, though they will lack a necessary ingredient: the transition between medical management of a case and the law. But the transition is short, and most important is the medical management of the case. Without some type of medical injury there rarely is an incident of malpractice. As such committees become experienced and sophisticated, new complexities and new solutions will emerge.

The physician in Connecticut must be prepared to try any reasonable means to combat "the malpractice crisis" before the quotes have to be removed.

Fred Fabro, M.D.

The Boston-Edelin Case

Sufficient time has elapsed since the Boston jury decision against Dr. Kenneth Edelin to permit editorial assessment of the impact of this widely publicized case on abortion practice in Connecticut. Just as the sentence was a minimum penalty and the chance of reversal on appeal seems great, the effect thus far on events within our state has been minimal.

The frequency of first trimester abortions continues at unchanged rates. The high utilization of this procedure reflects not only women's insistence on its legal availability and physician willingness to perform suction curettage but also the serious imperfections in the availability, application, and acceptance of contraceptive methods.

Similarly, the Boston decision has caused little modification of patient, physician, or institutional posture with respect to mid-trimester abortions. In some instances, the procedure has been abandoned entirely or strictly limited to pregnancies of less than 20 weeks' duration. Nevertheless, interruption up to 24 weeks is still performed in Connecticut. Strict adherence to this point of previability—and made possible by means of ultrasonic measurements—was a requirement which *preceded* the Edelin case decision and its publicity.

What next? Undoubtedly, relentless and escalating legal and legislative pressures will surround the abortion controversy. This will certainly include a court test of the individual woman's right to secure mid-trimester abortion vs. the physician and hospital obligation to sustain life in a case of borderline fetal viability. The philosophic and ethical implications of this problem extend beyond the issues of quality of survival, baby placement, and hospital costs. In all likelihood, there will be continued effort to establish legal status and guarantees for the previable conceptus, with ramifications involving contraception as well as abortion practice. How much better if all sides, in their own way and with their own constituencies, utilize all this time, energy, and money in behalf of *avoidance* of unwanted pregnancy.

The physician's role, whether or not he or she does abortions or approves of them, should be to counsel moderation in dealing with this issue. But there should be recognition of one pervasive historical principle—regardless of public statements to the contrary, women of all races and religions will resort to abortion to end unwanted pregnancy. Under no circumstances or pressure should women or their physicians accept return to the maternal morbidity and mortality inherent in the criminal abortions of the past.

Nathan Kase, M.D.
Yale University School of Medicine

Forrester's Law

A new social law that may rank alongside Parkinson's Law on the proliferation of bureaucracy is gaining acceptance in some technological quarters. Called Forrester's Law, this maxim holds that in complicated situations efforts to improve things often tend to make them worse, sometimes much worse, on occasion calamitous.

Dr. Jay W. Forrester, Professor of Management at the Massachusetts Institute of Technology—doesn't put the matter that bluntly of course. In M.I.T.'s "Technology Review," he writes of the "counter-intuitive behavior of social systems" which are "multiple loop, non-linear feedback mechanisms." Translated that means one ought to expect surprising and dismaying results from naive reforms that fail to take into account the many and diverse ways individuals and groups can react to even the simplest—let alone the most complex—change in the social environment.

Dr. Forrester, one of the world's great computer experts, discovered his "law" after long years of study of mathematical models of complex systems. He used computers to simulate the operation of social systems over many decades and discovered that frequently changes intended to improve matters made them worse, especially in the long run.

Many an average citizen, no doubt, has independently stumbled on the same discovery just by paying attention to what has been happening around him.

In education, for example, the nation has vastly increased its expenditures for new school buildings, new campuses, higher pay for teachers and the like. Yet never has there been so much dissatisfaction with the educational system among both students and taxpayers.

The disillusionment has reached such proportions that Ivan Illich has won national attention for extreme ideas summarized by the title of his recent book, "Deschooling Society." And even a more moderate figure, Wilson Riles, State Superintendent of Schools in California, now extols the virtues of the one-room schoolhouse and suggests it may "represent the wave of the future in education."

Nor is the situation much different in the medical field. The nation has more doctors, more allied medical personnel, more shiny gadgets to save lives, and more people eligible to get medical care without immediate out-of-pocket cost than ever before. Yet it is now a cliche to speak of the "health care crisis" and half a dozen or more schemes are before Congress for radically reorganizing American medicine.

But while the Congressmen, in blithe ignorance of Forrester's Law, want to improve medicine by making it more organized, more of a system, at least one doctor suggests that progress may lie in the opposite direction. In the prestigious *New England Journal of Medicine,* Dr. Michael J. Halberstam has recently written that improvement may come from making medicine much more of a "cottage industry," one in which more people could have intimate contact with their doctors than they can in today's emergency rooms, hospital outpatient clinics or the increasingly computerized and automated examination assembly lines of prepaid group medicine.

Other examples of Forrester's Law come easily to mind in diverse fields: the rising tide of crime and narcotics addiciton even as police forces and drug control programs are expanded; the increased sentiment for separatism among black militants in the generation since the Supreme Court decision outlawing school segregation, etc.

Bluntly stated, as it is at the beginning of this article, Forrester's Law may seem a counsel of despair, an injunction to accept even an unsatisfactory *status quo* because any change will be worse.

But Dr. Forrester himself is more optimistic. He believes improvements can be made in the nation's problems if alternatives are explored methodically and carefully—using mathematical models and computers—with a view to spotting possible and hitherto unexpected backlashes or negative results before they become reality.

Politicians, however, are always under pressure to produce quick, facile solutions, and political debate rarely extends even to the limits of the average citizen's common sense and intuition. Nevertheless Professor Forrester's ideas seem worth serious trial. The cost of the kind of computer experimentation he recommends is infinitesimal as against the price society is now paying for its past adoption of the mistaken policies that have produced many of today's thorny problems.

A start might be made by analyzing the newly fashionable proposal to make New York City the 51st state. Would such a change help meet the city's problems or would it worsen them beyond repair? Perhaps Prof. Forrester with his equations and his computers could help throw light on those vital questions before the overblown rhetoric of political debate prevents rational consideration of the pros and cons of an exceedingly complicated issue.

Harry Schwartz, Ph.D.

Dr. Schwartz is one of the nation's foremost writers on medicine and economics, and has been a member of The New York Times *editorial board for many years.*

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Letters To The Editor

Letters to the Editor are welcomed and will be published, if found suitable, as space permits. Like other material submitted for publication, they must be typewritten *double spaced* (including references), must not exceed 1½ pages in length and will be subject to editing and possible abridgment.

MEDICINE IN THE BOONDOCKS

To the Editor: I don't know how often a person responds to his own editorial, but during the gestation of my piece "Who Are the Good Guys?" in the January issue of *Connecticut Medicine*, some months passed and I was able to read it with some objectivity.

As I read it, so to speak, anew, one point seemed to rear its head. The only chance we will have to find some good guys (i.e. referees, including ourselves, whom we will trust to evaluate our performance) will be with the true spirit of cooperation of the non-professional members of the hospital staff, the Hospital Board and the consumers of medical service.

If our attempts at self improvement are to be honest, they will obviously turn up shortcomings in our care: that is what we are trying to do.

If non-medical groups are sincerely anxious to improve medical care, they will work with us and respect these efforts at self-appraisal. If any of them succumb to the temptation of using our own attempts at self-criticism against us, they will produce a climate of mistrust that will be counter-productive in the extreme.

John L. Meyer II, M.D.

Putnam, CT.

FLU VACCINE—QUESTION OF INTRADERMAL

To the Editor: Dr. Kraus (Conn. Med. 39: 162, March, 1975) brought out the fact that 1 cc. of influenza virus vaccination is superior to 0.1 cc. or more intradermally. (The Army method is superior to the Navy method.) After many years of routine influenza vaccinations and titer studies, I have discovered that results of 10 X a dose does *not* increase the protection 10 X.

In fact, my colleagues who have used the 1cc. 1m. dose do not get patient to repeat immunization the next year because of reaction, fever, sore arm and flu-like symptoms. This rarely follows intradermal injection—only reaction being urticarial.

One sure way to destroy an immunization program is to make many sick with vaccine. They never return.

Actually it is the viral composition of the flu vaccine that determines its value along with number of injections.

I have found great educational health possibilities with the intradermal method which would never clinically follow the 1 cc. injection along with more than 1/10 titer increase of 1 cc. dose.

Bernard S. Dignam, M.D.

Enfield, CT.

The above letter was referred to Dr. Kraus, who offers the following reply:

To the Editor: My comments concerning the use of influenza vaccine by the intramuscular route did not mention using one cc. of influenza vaccine. The newer purified vaccines are given in doses of 0.5 cc. and it has been the experience of physicians who use this method that the incidence of reactions is both minimal and mild.

I would suggest that Dr. Dignam inform his colleagues who have used one cc. of influenza vaccine to discontinue the procedure and use the purified vaccine in doses of 0.5 cc.

I have also been under the impression that we do not use influenza vaccinations for health education but for the prevention of the disease itself.

The point I was trying to make in my comments was that there is presently proof that influenza antibody levels resulting from intradermal injections are definitely lower than those produced by the subcutaneous and intramuscular routes. If Dr. Dignam has any proof to the contrary, I should be interested in knowing where it has been published.

George Kraus, M.D.

Director of Health
Greenwich, CT.

PRIMARY CARE QUESTIONNAIRE

To the Editor: On behalf of the Commission on Hospitals and Health Care and the members of the Task Force on Primary Care we wish to express our appreciation to those primary care physicians—general practitioners, family physicians, internists, pediatricians and obstetrician-gynecologists—who generously responded to the primary care questionnaire, initially distributed in November, 1974.

These responses have provided critical data for the planning of primary health care services in the state as a whole as well as in the various localities of the state. The application of this material may prove of inestimable benefit to pinpointing areas of need for both providers and recipients of care.

The subcommittee on the Distribution of Physicians and Dentists, chaired by James E. C. Walker, M.D., perceived a need for developing a quantification of the existing availability of primary care services beyond what is currently available through licensure and other enumeration. They also recognized that availability had to be determined on the local level where primary care is sought and provided and where the most accurate analyses of the amount of primary care can be made. When the discrepancies between needed services and available services by geographic area have been defined, rational attempts can be made to fill the gap in the shortage areas on a priority basis.

As detailed in a letter to the Editor in the April issue of *Connecticut Medicine*, a range of essential data most critical to ascertaining availability of primary care was sought. This included such general information as age, sex, and specialty and more specific knowledge relative to practice setting, time devoted to direct primary care, etc.

We are most gratified at the unique response rate of over 75 percent and the indication of widespread interest in our study.

We welcome your comments and suggestions and look forward to sharing the final analysis of data in our completed study with all concerned physicians.

Sarah S. Hirakis, M.P.H.
Deputy Director, Health Planning Division

Commission on Hospitals and Health Care
Hartford, CT.

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Medical Society Ordered to Reinstate Member

The expulsion of a physician from a county medical society after his conviction for a felony has been declared invalid. A Florida appellate court pointed out that state law requires a member of a nonprofit organization to be given a hearing before his membership can be terminated.

The Dade County Medical Association acted in accordance with its bylaw which automatically terminates the membership of a physician convicted of a crime involving moral turpitude. The doctor, Harry Needelman, claimed that his conviction on a charge of violating a federal narcotics law did not involve moral turpitude, and that he had received a Presidential pardon, which, he said, wiped out his guilt.

In ordering Dr. Needelman's reinstatement, the court noted that the medical association's bylaw might be denying its members a valuable right. Although the facts of a member's conduct may not be in doubt, the court commented, a hearing gives him the opportunity to present facts about his motives or in extenuation of his conduct. Those facts might have some bearing on the final decision reached by the organization.

PSRO and the Quality of Health Care

Henry E. Simmons, M.D., M.P.H.

The multitude of problems evident in the health care system in this country has given rise to a number of health initiatives at the Federal, State and local levels. They include examination of possible financing mechanisms through national health insurance, area-wide health planning, expanded delivery systems such as Health Maintenance Organizations, new health manpower proposals, health education programs, new drug and device legislation, various approaches to the joint problems of malpractice and defensive medicine and the Professional Standards Review Organization (PSRO) program.

PSRO is potentially the most important of all these programs for it can be a mechanism for helping to solve many of the problems existing in today's health care system and for improving the quality of medical care provided the American people. The program gives the medical profession the opportunity to set standards of care, monitor themselves to see that those standards are met, and to work to correct any shortcomings in the performance of its members through educational programs.

The Federal Government spends about $20 billion annually to provide health care under the Medicare, Medicaid and Maternal and Child Health programs. Most of that care is of high quality, but some of it is not. The average citizen cannot usually evaluate the quality of care he receives or for which his tax dollars pay, but the practicing physician most surely can. PSRO, then, is an effort to make the review of Federally financed medical services more effective by involving in that review those best qualified to monitor and evaluate medical services—local physicians. These physicians are asked to set up and operate local organizations to review care provided in institutions with Federal funds to see that the care is necessary, of acceptable quality and delivered in the most appropriate setting.

The quality of medical care is very uneven and in too many instances falls below what the majority of physicians recognize as appropriate. PSRO gives us opportunity to look objectively at many of the problems facing us today. The difference between what we know should and could be done and what is being done in many areas is wide and growing wider. There is evidence that our expensive health resources, both manpower and facilities, are inefficiently and inappropriately utilized and, in fact, some of our critics would use the words "irrationally utilized."

The PSRO legislation, as simply as I can put it, calls for groups of local physicians in defined geographic areas to take on the following responsibilities: (1) to develop standards; in other words the profession, on the basis of its best judgment, the medical literature and on its experience, is to determine what is appropriate to deliver to a particular patient in a specific setting; (2) to then see that the care rendered in their area and paid for with government tax dollars is compatible with those standards and is rendered in the most appropriate setting; (3) to see that those standards are modified as appropriate; and (4) to take appropriate action in instances where care is rendered outside those standards—and that does not automatically mean punitive action. It means finding out why care was rendered outside the standards and, in the many instances where it will be found to be appropriate, allowing that kind of care to be delivered and paid for. In instances where it is not appropriate, to see that it does not happen again. The profession has that responsibility, and it carries out that responsibility primarily through educational efforts.

PSRO is responsible for utilization review, which it accomplishes by establishing critical standards for admission and carrying on concurrent review during that admission as well as seeing that discharge planning is conducted. But PSRO is much more than utilization review, and in fact utilization review is probably the smallest part of what PSRO's will be doing. It is that fact that makes this a unique program. For in addition to utilization review, PSRO's are required to carry out retrospective medical care evaluation studies to determine what care was rendered during the admission. Was it appropriate to the need? Did it meet established standards? And most importantly, what was the outcome of the care rendered? And through those medical care evaluation studies and the development and analysis of profiles of institutions, patients and providers in its area, the PSRO will be able to identify trends, unusual variations in patterns of care, or outcomes of care among providers. Having identified these factors, it is charged with the responsibility to evaluate why differences exist, why some outcomes are poor, what care is being rendered in sub-standard or unusual fashion, and on the basis of such study, to take appropriate corrective action in the public interest.

So PSRO is an orderly mechanism through which all medical care will be assessed by our profession. For

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DR. HENRY E. SIMMONS, Acting Deputy Assistant Secretary for Health, and Director, Office of Professional Standards Review, U.S. Department of Health, Education, and Welfare, Washington, D.C.

the first time with PSRO our profession will know what is going on and why it is going on, not only in an individual institution, but in an entire area for which it is responsible, and, in addition, be able to bring about changes where they are appropriate. It is an educational tool that will channel its efforts in the areas where solid data indicate that there are problems. Hospitals will actually learn from each other, and one area will learn from other areas. It lets the profession take a step outside its own hospital walls to get a broader view, to take a view across areas, to take a view across the country, because PSRO data will be shared with other PSRO's. In addition, PSRO will build on existing systems. It will utilize those effective utilization review committees which are currently at work in the Nation's hospitals.

In areas where PSRO's are not yet actually reviewing medical care, there is an interim measure in effect. To strengthen the quality assurance mechanism within our country's hospitals as it affects Medicare and Medicaid beneficiaries, the Department published on November 29, 1974, regulations which set forth expanded requirements for utilization review in hospitals and other health care institutions as a condition of participation in the Federally financed programs. These regulations will help assure a smooth transition to the PSRO review requirements and for the first time establish a uniform utilization review system for both Medicare and Medicaid which is compatible with and supportive of PSRO and will become an integral part of the PSRO program. The new regulations place increased responsibility upon the hospital for conducting concurrent review and retrospective medical audit. The regulations apply to hospitals in areas where no Conditional PSRO has yet been designated. In those areas where Planning PSRO's have matured into Conditional PSRO's and are effectively carrying out the responsibility for medical care review, the PSRO review system takes precedence over these regulations. Under the PSRO system, however, many hospitals can still be delegated review responsibilities provided that they demonstrate the capability and willingness to do so, and provide that the hospital staff are members of and active in the PSRO.

With regard to the medical care evaluation studies required by the Utilization Review Regulations, at least one study must be in progress in an institution at all times, and at least one study must be completed each year. The hospital Utilization Review Committee must document both the results of each medical care evaluation study and how the results have been used to institute changes to improve the quality of care and promote more effective and efficient use of facilities and services. Thus, the Utilization Review Regulations will substantially strengthen the current review process in hospitals. However, even with the new Utilization Review Regulations, the advantages of the PSRO system still pertain. Current utilization review committees continue to make recommendations to fiscal agents. The fiscal agents are not bound by those recommendations. Only under PSRO is final decision-making responsibility transferred to the physicians, and only under PSRO is there the opportunity to build a community-wide system of peer review for services provided in all settings. Hospital utilization review, then, no matter how well performed, will not substitute for PSRO. The PSRO retains the final authority and responsibility for setting the standards and norms to be used, decisions as to delegation or withdrawal of delegation, and oversight of the adequacy of review in instances where it is delegated.

PSRO physicians will select, develop and be responsible for the ongoing modification of norms, criteria and standards to be used in reviewing care. There will be no national standards. The standards will be those of the more than 200 PSRO's in the country.

The norms, criteria and standards of care developed by local physicians will not be cast in concrete to remain forever as the absolute determinants of care. Rather, they will be flexible and will serve as checkpoints which identify instances of care that fall outisde what would normally be expected to occur. These checkpoints will be established for classes of patients with a particular diagnosis or problem. When applied, they screen out cases requiring more in-depth review. It is at this point that peer review really comes into play. All factors related to the particular case in question must be considered before any decision affecting payment by the Federal Government is made. For example, consideration of the patient's psychological and social situation and the availability of alternative facilities must be considered as, of course, must the distinction between the case in question and the criteria themselves.

Innovation will not be stifled, for there is every room for experimentation in the PSRO program. What will be different is that experimentation will be carried out as such, under an adequate protocol, with informed consent, and done in such a way that the individual doing the experiment, the public, and the medical profession will have at the end of the experiment an answer that is useful. Experimentation will not be done in such a haphazard way—as it is oftentimes today—that at the end of the experiment no one knows exactly what has transpired or is able to draw a cause and effect relationship from what was done.

The issue of confidentiality which is often raised in connection with the PSRO program is a potential problem, not only in our present Medicare and

Medicaid programs and in existing private health insurance plans, but throughout our society. The PSRO legislation contains strong penalties for breach of confidentiality. With the help of experts and affected organizations, we are currently developing guidelines and regulations that will address confidentiality in very specific terms. These guidelines will be made available to the PSRO's, to data processors who support PSRO's and other involved groups. Their application will be mandatory for all PSRO's and all groups that handle data for any PSRO.

The privacy of patients and physicians is a basic civil right and must be respected. Medical records contain a great deal of privileged information, but the data collected for PSRO purposes will be limited to that required for review. While the law requires the development of patient and physician profiles, the identity of the individuals will be protected from disclosure. There will be no national data bank of individual patient records, and everything possible will be done to protect the confidential nature of any records maintained on a local level.

There is nothing in the philosophy, structure or operational requirements of the PSRO program that should interfere with the traditional practice of medicine or with traditional doctor-patient relationships. Local physicians will review patient records, and all final review determination will be made by physicians.

Professional Standards Review Organizations have the potential for reducing malpractice incidents, patient injury based on those incidents, and legal action because of those injuries. In addition, the program is likely to decrease the incidence of defensive medicine, that is, medically unjustified care provided solely to reduce the possibility of a malpractice suit.

These results will flow, in the first case, from the increase in quality of medical care services that can be expected to occur as review of those services becomes general; that is, as quality of care increases, the number of malpractice suits should decrease. In the second case, the practice of defensive medicine should decline as physicians gain confidence in PSRO developed norms and standards of care and begin to abandon the over-utilization prompted by the fear of suit.

The civil immunity provision of the PSRO Act, which grants limited immunity from civil liability to health care providers who adhere to PSRO norms and standards, will be useful in both regards. As an incentive for physicians to comply with PSRO, it will aid in the review and enchancement of the quality of care; by providing immunity only if the standards are followed, it will clearly indicate that utilization beyond the standards is unnecessary from either medical or legal viewpoints.

The greatest impact of PSRO on malpractice, however, will be evident in its role in the demise of the malpractice system. Fully operational PSRO's will be more efficient than the malpractice system in controlling and assuring the outcomes of medical care.

There was, in the past, some concern within the medical profession about the impact of the PSRO program on the practice of medicine. I believe that most of the country's physicians now support the basic concept of PSRO and will participate in the implementation of the program. At present, there are 14 Conditional PSRO's. During the spring of 1975, we will be reviewing applications from the 91 present Planning PSRO's who wish to attain Conditional PSRO status. It is anticipated that somewhere between 30 and 50 of these organizations will assume review responsibility in the near future. Other present Planning PSRO's will remain in the planning phase. At the same time, there are approximately 40 to 60 new organizations wishing to become Planning PSRO's, although our budget constraints will allow us to fund only about 20 new Planning PSRO's during the current fiscal year.

Other activities to improve medical care quality are also underway. The National Health Planning and Resources Development Act of 1974 was signed into law on January 4, 1975. The new law will replace the old Comprehensive Health Planning, Regional Medical Program, and the Hill-Burton programs with a combined scheme of national health planning through local agencies to be known as Health Systems Agencies (HSA) and State Planning and Development Agencies. Such agencies will review health care resources within a specific health service area. Those areas will generally be somewhat larger than PSRO areas and will usually contain a population of 5 hundred thousand to 3 million. It is hoped, however, that most planning areas will be coterminous with PSRO areas, perhaps containing two or more PSRO's. The relationship and interaction between PSRO and HSA will develop out of their separate but equally important tasks. The PSRO will determine the quality and necessity of medical care being delivered in a particular area. It will forward data and possibly recommendations to the Health Systems Agency for its consideration in planning for improvement of medical care delivery. PSRO's and HSA's are supportive of each other. The HSA does not look at the way individual transactions occur or the way providers treat individual patients. They will look at the way the system is working as a whole and the way medical care is being delivered in the aggregate and at who the institutions serve and who they do not serve.

With health planning legislation presently being implemented and with health manpower legislation under very active consideration in both Houses of Congress, we anticipate an even greater interest in Professional Standards Review Organization. Health manpower and facility planning, along with PSRO, are essential in order to build a solid base for any national health insurance plan. Through the cooperative effort of the private and public sectors, we can unify, systematize and make rational use of the health resources available to us. The success of that effort will depend in large measure upon the extent to which the Nation's physicians participate in PSRO and the other programs aimed at improving our country's health care delivery system.

Malpractice Suits Hurt

Connecticut has yet to experience a real crisis, such as those in California, Florida and New York, over the soaring costs of medical malpractice insurance. But this problem does take money from our pockets, and unless it is checked, it will take even more.

In 1974, the number of malpractice suits in this country increased by 73 per cent, and the amount of money awarded grew by 20 per cent. Travelers President Morrison H. Beach predicts that his companies' premiums in Southern California, a particularly critical area, may increase as much as five times in the next year. Other companies are charging doctors as much as $14,000 a year in certain high-risk specialties. Others are pulling out of the field, leaving doctors with no coverage at all.

That's only one part of the problem. In order to pay their stiff premiums, doctors will have to boost their fees. That will mean higher medical bills and higher premiums for personal health insurance.

Some doctors are being forced to leave practices in low-income areas to seek higher incomes for themselves. Some have grown overcautious, ordering extra tests at extra expense. Others are shunning potentially lifesaving new techniques which have not yet been proven risk-free.

A solution will require the cooperation of doctors, lawyers, insurors and government, groups which now approach each other with a growing sense of mistrust. All hold some responsibility for the problem, and all must work to solve it.

The medical profession's greatest responsibility is to police itself better and get rid of its greedy or incompetent members. Lawyers have much the same duty. Malpractice has attracted a new breed of ambulance-chasers to a field where 70 per cent of the average court award is eaten up in legal fees and other costs.

Governments, particularly state governments, must play important roles, too. Initially, they can authorize insurance pools so doctors can at least obtain coverage. Some direct financial aid might also be necessary.

Government also holds the important controls of professional licensing and insurance regulation. It might seek to apply to malpractice the principles of no-fault auto insurance: Better protection against real economic losses, and less money for pain, suffering and court costs.

Other possible remedies include shorter time limits for filing claims, and mediation panels to help make more equitable claim settlements.

The public can help, too, by refusing to be goaded into seeking sudden riches from malpractice claims, and asking only for fair reasonable compensation.

The malpractice crisis has no single cause, and there will be no one, simple remedy. Everyone involved must accept a full share of responsibility for relief. Otherwise, we will all find ourselves paying more and more money for less and less good medical care.

—Hartford Courant

Experimentation with Human Beings—Values in Conflict

Jay Katz, M.D.

The controversy over the use of human beings in medical experimentation demonstrates the difficulty of reconciling two values basic to Western society: the desire to benefit as quickly as possible from advances in medical knowledge, so that we can live longer and in good health, and the commitment to individual dignity and autonomy which makes us uneasy whenever anything is done to a person without his informed consent.

To safeguard the second value, HEW regulations require that subjects of research be apprised of the proposed research procedures, their discomforts and risks, and their right to ask questions and to withdraw their consent at any time. They are also to be informed, if they are both subjects and patients, of the benefits to be expected and the alternatives available to them. These obligations find support in the great weight American laws give to the proposition, expressed succinctly by Justice Cardozo: "Every human being of adult years and sound mind has a right to determine what shall be done with his body."[1]

The requirement of informed consent, however, has not been enthusiastically endorsed by the research community. Medical investigators in particular argue that subjects of experimentation are already, and indeed best protected by the Hippocratic commandment to physicians "above all, do no harm." In invoking this principle, investigators overlook that the issue is not merely the protection from physical harm but also, and first of all, the protection of the subjects' rights to make their own decisions about everything affecting their lives. The concern over risks and attempts to minimize them can only be applauded. But these efforts must not lead to the paternalistic conclusion that once scrupulous care is taken to avoid "unnecessary" harm, investigators and not subjects should become final decision-makers.

Investigators frequently assert that "informed consent" is meaningless because many subjects do not understand what is being asked of them. To the extent to which this assertion is correct, it raises grave questions about allowing uncomprehending subjects to participate in research. However, investigators admit less frequently that the obligation to disclose creates problems all its own. Informed consent imposes a dual obligation, to inform and to obtain consent, though in most discussions the emphasis shifts too quickly from disclosure to consent.

Indeed, it is disclosure which may have to be given greater weight than consent in the promulgation and review of the informed consent requirement. Criteria for disclosure can be formulated and the performance of the obligation to disclose can be objectively assessed. Meaningful consent, on the other hand, is more difficult to evaluate, if only because subjects themselves may find it hard to articulate the reasons for their decisions. The choices, however idiosyncratic, of legally competent subjects must be respected so long as a prior attempt at adequate disclosure has been made. Indeed, ultimately informed consent will only be a meaningful prescription if investigators view subjects as co-decision-makers, and thus will inform them in the context of a respectful dialogue between co-adventurers and not of a senseless ritual to be rushed through as quickly as possible.

However, the shift from disclosure to consent has other implications. A thoroughgoing commitment to disclosure brings to the surface "practical" and psychological problems. Complete disclosure increases the time that must be spent with potential subjects. It will also take longer to obtain the requisite number of subjects, for more will refuse participation. Some research projects may have to be abandoned for want of consenting subjects or because the experimental design requires deception of which the subjects cannot be informed. Thus the advancement of medical knowledge, from which so many of us wish to benefit, may be impeded. It is this "practical" problem which makes everybody, and not only scientists, uneasy about disclosure.

The reluctance to disclose fully has also a very personal psychological dimension. Consider what must be communicated by investigators and with what kind of an attitude, if participation is viewed as a genuine invitation that could be accepted or rejected by the subject of research. It would necessitate sharing knowledge and admitting uncertainty and ignorance, answering all questions and identifying unanswerable questions, appreciating doubts and respecting fears. It is indeed an awesome encounter if engaged in honestly. Thus the controversy over the *subject's* incapacity to understand, on which the debate about informed consent has focused, is in part a denial of the *investigator's* dread to engage in a searching and explicit dialogue with his subject.

Fidelity to the rights of research subjects may impede experimentation or indeed may make some research impossible to conduct. If we wish to avoid such consequences, and to authorize an invasion of

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individual dignity and autonomy only under well-defined circumstances, many questions must be faced: Who should decide when to tamper with basic rights of individuals that law otherwise seeks to protect? Should such decisions be left solely to investigators or to the scientific community? Can society at large, on behalf of the affected subjects, give its "informed consent" to the tolerable limits scientists can go in the use of human beings? What are the human costs society is willing to underwrite in order to obtain the medical and technological advances that it seems to want so badly?

It is imperative that answers to these questions be sought by members of many disciplines in cooperative inquiry. The competing values at work in human experimentation must be identified so that we can decide more consciously which to neglect and which to safeguard.

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Fetal Research Aids Infants

Last year Congress ordered a moratorium on fetal research and set up a commission to recommend legislation protecting a premature baby's rights. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research will not be able to meet the April 30 deadline assigned to it because public hearings must be held. Nevertheless, the commission has called for the immediate repeal of the moratorium so that studies may proceed which do no harm to a viable fetus and with the informed consent of the mother. Lifting the ban could enhance the prospect of healthier babies for generations.

There are two kinds of research involved. One is therapeutical in nature, intended to be beneficial toward the fetus or toward the pregnant woman, sometimes with life-saving results. The other, nontherapeutic, involves objectives which have no prospect of helping the one studied, but offer life-saving information for another. An example would be to study the function of normal lungs in one fetus to provide help for another whose breathing apparatus malfunctioned.

Therapeutic research under proper circumstances is encouraged by the commission. Nontherapeutic research is more controversial, thus needs even more stringent guidelines. Circumstances are to be spelled out in the commission's final report to Health, Education and Welfare Secretary Caspar Weinberger after the hearings. At present these rules are directed toward the pregnant woman, the fetus in the womb, the possibly viable infant, the fetus during an abortion and one already removed from the womb when there is no apparent chance of its survival. Strict restraints are listed for these and other conditions.

While Americans are rightfully concerned about protecting life, they also know how vital it is to continue without destructive interruptions scientific studies into the ills of man. The National Foundation's annual report said as many as half of the patients in most children's hospitals today have diseases directly or indirectly caused by a birth defect. It also notes that there are "some 500,000 spontaneous abortions, stillbirths and miscarriages each year due to defective fetal development.

Furthermore, birth defects affect the lives of some 15 million Americans alone with 1.2 million of them hospitalized every year for treatment. Biochemical research has detected 32 inborn fetal metabolic errors. The study of what appears to be a basic enzyme defect in cystic fibrosis "may revolutionize the diagnosis and treatment of this most common genetic disease of Caucasions," the report said.

Transplants of the liver and of the thymus in recent years have corrected immune deficiencies in youngsters who would surely have died if fetal organs were denied them. Those organs come from fetuses as young as in the ninth week of development. Life for the fetus was beyond anticipating. Life for the recipients still thrives. Rigid regulations, carefully enforced and supervised, are indeed imperative. But research must go on that more youngsters can lead healthy lives beginning at birth.

—*Hartford Courant*

The Interface Between Podiatry and Medicine

Irving Yale, D.P.M.

The profession of medicine must take a clear and objective look at its sister profession—podiatry.

"We in the podiatry profession consider that good foot health is a right of the American public and that it is our privilege to help assure it. Indeed, in a little over half a century—just a fleeting second in the history of mankind—the podiatrists of America have made significant contributions to the life of the nation." (Yale 1967)

Podiatry has a well-rounded effective enthusiastic professional team. Seventy-five per cent (75%) of all podiatrists and 85% of those in active practice are members of the American Podiatry Association. It is exciting, and possibly a record for professional organizations, that 90% of all graduates from Colleges of Podiatric Medicine join the American Podiatry Association and 98% plus retain their membership during their productive years and into retirement. (Pankratz 1973)

In 1966 the House of Delegates of the American Podiatry Association adopted the following statement, "Podiatry is that profession of the health sciences which deals with the examination, diagnosis, treatment, prevention and care of conditions and functions of the human foot by medical, surgical and other scientific methods." This definition was not developed as a goal. It was indeed a conclusion based on a careful view of past, present and projected state statutes, courses of study on an undergraduate level, and future objectives for graduate and continuing education. We proudly affirm that podiatry is different from medicine; witness our skills in palliation, strapping, padding, biomechanics, open and closed surgical techniques, as well as the total concept of foot care. Yet, our basic training in medical science is the same as medicines with a strong and highly specialized concern for the diagnosis and treatment of foot disorders. Connecticut Statutes, Section 20-50, reads as follows:

Podiatry is defined to be the diagnosis, prevention and treatment of foot ailments including the prescription, administering and dispensing controlled substances in Schedules II, III, IV or V in connection therewith, the practice of minor surgery upon the feet, including all structures of the forefoot forward of the tarsal bones, but excluding operations on the bones of the tarsus, without the administration of an anesthetic other than a local anesthetic; the dressing, padding and strapping of the feet; the making of models of the feet and the palliative and mechanical treatment of functional and structural ailments of the foot, not including the amputation of the leg, foot or toes or the treatment of systemic diseases of the bones, ligaments or muscles of the feet or any other part of the body.

The highly qualified new era podiatrists, the majority of whom hold a baccalaureate degree or higher, and an additional four academic years at a College of Podiatric Medicine, find it difficult to come to Connecticut to practice. In most cases, they continue on to a residency at an accredited general or specialty hospital and often specialize for another one or two years in sophisticated diagnostic training, biomechanical treatment of the foot and reconstructive foot surgery. Most of these fine capable young men do not return to Connecticut where the unwieldly statutes are limiting and hospital privileges are wanting.

The House of Delegates of the Student American Medical Association (SAMA) has recognized podiatric medicine as a separate professional field of medical practice, and has expressed a wish to establish formal liaison with the American Podiatry Students' Association (APSA).

The action was taken in early March 1974, in Dallas, Texas, at a SAMA meeting.

The SAMA resolution cited lack of contact in the past between SAMA and APSA members as a reason for "the inappropriate exclusion of the podiatrist from active patient care within the traditional hospital setting."

As in the practice of medicine the podiatrist knows his limitations and recognizes his responsibilities. Only the professions of medicine, osteopathy, dentistry and podiatry are licensed to independently diagnose and treat medically and surgically.

The podiatric generalist is qualified to administer medical and surgical treatment of the most common diseases and disorders of the foot. There are some podiatrists who devote most of their practice time to treating the geriatric patient. Riccitelli (1966) in a fine paper on the foot problems of the geriatric patient states "In elderly people, especially those with diabetes or peripheral vascular disease, foot care is mandatory." He also notes that, "Foot problems, long neglected by

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the medical profession, have now become a major concern in the total care of the aged and infirm . . . ."

Podo-pediatrics concerns itself with the foot care of children. The sophistication of structural and functional treatment of foot disorders requires the skills of a life-time devotion to the study of feet.

The majority of diseases, deformities and sequela of trauma affecting the feet disturb them as organs of locomotion and weight bearing. The biomechanical treatment of feet through a well plotted mechano-surgical regime helps maintain the pedal extremities in the best structural position for improvement of function.

Podell (1971) in, "An Illustrative Case Study—Podiatry in the United States," has shown that, despite millions of Americans visiting podiatrists each year, "their physicians have little idea of who the podiatrist is and what he does!"

The podiatrist must be a skilled diagnostician in his highly specialized field. He is well trained in the interpretation of local manifestations of systemic disease and his professional ethics and judgment insist that consultation with the other medical specialists is mandatory. This philosophy is well documented and needs no further discussion here. In the new book "Podiatric Medicine" no fewer than 36 statements are made referring patients to the internist and other specialists in medicine.

If the average medical doctor was asked what a podiatrist does in his office he would most likely reply, "he treats corns, calluses and ingrown toenails." There are very few feet with symptoms of superficial excrescenses that do not present primary pathology in connective tissues other than skin. That sounds simple enough on the surface but let me briefly illustrate what it entails with the least sophistication.

Treatment of a painful corn (heloma) commences with a differential diagnosis to establish its presence. A complete examination covers all bases e.g., peripheral vascular, neurological, X-ray, biomechanical and laboratory studies when necessary.

The heloma may be hard or soft dependent on a variety of environmental conditions. In fact it may not be a heloma at all but possibly a mosaic verruca, a verruca vulgaris, a keloid, poroma, intractable keratosis, cutaneous mucoid cyst, senile keratosis, or psoriatic scale accompanied by multiple complications. The skilled podiatrist is faced with differentiating the discomfort of a heloma from traumatic acute bursitis, a synovitis, extraskeletal calcification, degenerative joint disease involving the interphalangeal articulations, tophaceous deposits of gout, effusions of rheumatoid arthritis, pyogenic arthritis secondary to an ulceration or infected sinus tract, ainhum, a fracture, dislocation, hammer toe, tenosynovitis or possibly a neuroma or an ischemic neuritis. Obviously, the treatment of this heloma takes on a serious note of professional judgment that can only be handled by skilled doctors who specialize in the diagnosis and treatment of foot disorders. The use of conservative palliative methods of treatment is sometimes wanting and the correction of these helomas and their cutaneous and subcutaneous complications may embody reduction, shielding, injection therapy, excision of masses, correction of deformed toes, arthroplasty, exostectomy physical therapy and often systemic analgesics and anti-inflammatory agents. Many casting techniques are used to construct toe jackets and devices to protect the affected area. These are made of latex foam, plastics and acrylics. The structurally disturbed foot may have to be corrected in an effort to remove undue stress on the affected parts. Orthotic devices are constructed over plaster impressions of malfunctioning feet.

Further discussion is not the intent of this paper. However, medical doctors should know the nature of the services rendered by the podiatrist and I address myself to the most common services the podiatrist renders. Each technique presents a variety of therapeutic approaches. Calluses (Tylomas) commonly seen on the ball of the foot are seen at a variety of locations and in sizes, shapes and complications not unlike helomas. Treatment again depends on the etiology and complicating structural and functional foot disorders. It may not only require reduction by scalpel, shielding, padding, and construction of orthotic devices, but often necessitates the surgical correction of hallux abducto valgus, exostectomy, metatarsal osteotomy and other sophisticated radiographically plotted foot surgery by qualified well trained podiatric surgeons.

As a doctor of medicine you may well ask, "By what background and accreditation do these foot doctors perform the services entitled by law?" As a podiatrist interested in improving our communications, I was hoping you would ask!

First let us establish a base at the educational level. There are five colleges of podiatric medicine in the United States, all fully accredited by the Council on Podiatric Education of the American Podiatry Association. The Council on Podiatric Education is accredited as an accrediting agency by the same agency, The National Commission on Accrediting, that accredits the accrediting body that evaluates colleges of medicine. The minimum requirements for acceptance at a college of podiatric medicine are sixty semester hours or a minimum two years at an accredited college or university with certain specific requirements in the sciences. Pre-podiatry undergraduate requirements are approximately the same as pre-medical undergraduate requirements. Since the applicants for admission exceed those accepted by 4 to 1, a majority of those matriculated hold a bachelor's degree or higher. The course of study at a college of podiatric medicine is four years, after which the student receives a standardized degree of D.P.M., Doctor of Podiatric Medicine.

Post-doctoral training consists of residency programs that are being rapidly expanded in Joint Commission Accredited Hospitals. Those programs affiliated with a degree conferring institution award a degree of Master of Science in podiatric surgery after completion of post-graduate study.

The podiatric curriculum consists of two pre-clinical years and two clinical years. Basic science instruction is equivalent in quality and quantity to that offered in traditional schools of medicine. Each of the colleges has its own foot clinics and affiliated hospitals.

The foot clinics of Chicago for example consistantly see over 50,000 patient visits annually in its departmentalized 12 story facility. One college has its own highly specialized hospital. Another has just opened its new nine million dollar scientifically oriented facility with an extensive program in community health. During the third and fourth clinical years, students are assigned to rotation in the departments of medicine, general surgery, podiatric surgery, podiatric medicine and podiatric biomechanics. A new college of podiatric medicine has been funded by the State of New York and will be located at Stony Brook as part of the State University of New York (SUNY). Several medical colleges have appointed podiatrists to their faculty as instructors or assistant and associate professors of podiatric medicine. Hundreds of A.M.A. Approved and Joint Commission Accredited Hospitals have accorded podiatrists meaningful medical and surgical privileges. We seek the same kind of forward looking cooperative spirit from medicine and state agencies in Connecticut.

A typical curriculum at a college of podiatric medicine is as follows:

FIRST YEAR CURRICULUM

Gross Anatomy
Microscopic and Developmental Anatomy
Neuroanatomy
Biochemistry
Physiology
Introduction to Podiatric Biomechanics
Introduction to Podiatric Surgery
Introduction to the Profession of Podiatric Medicine
Orientation.

SECOND YEAR CURRICULUM

Microbiology and Immunology
Pathology
Pharmacology
Physical Diagnosis
Podiatric Medicine
Podiatric Biomechanics
Epidemiology and Biostatistics
Podiatric and General Radiology
Clinic Observation

THIRD YEAR CURRICULUM

Podiatric Surgery
Podiatric Biomechanics
Dermatology
Orthopedic Surgery and Traumatology
General and Peripheral Vascular Surgery
Neurology
Internal Medicine
Clinical Therapeutics and Pharmacology
Podiatric Radiology Conference
Plastic and Reconstructive Surgery
Clinical Assignments (Medicine, Radiology and Podiatric Medicine, Surgery and Biomechanics)

In addition, the following elective courses are available:

Local Anesthesia and Therapeutic Injections
Plethysmograph
Special Studies

FOURTH YEAR CURRICULUM

Anesthesiology
Regional Surgical Anatomy
Practice Administration
Private Office Clerkship
Clinical Therapeutics
Clinical Assignments (at the C.C.P.M., University of California Medical Center, San Francisco V.A. Hospital, and other facilities—in Medicine, Radiology, and Podiatric Medicine, Surgery, and Biomechanics)

Elective Courses and Assignments:

Private Office Clerkship
Home Care Service, U.C. Medical Center
U.S. Marine Corps Recruit Depot, San Diego
V.A. Hospital, Leavenworth, Kansas
California Podiatry Hospital and Outpatient Department

During the third and fourth years, students are assigned to rotations in the Departments of Medicine, Podiatric Surgery, Podiatric Medicine, and Podiatric Biomechanics.

RESIDENCY

Although residency training is required only in the states of Michigan, New Jersey, Rhode Island, West Virginia and Oklahoma, most graduates apply for such programs upon completion of a course of study leading to the degree of Doctor of Podiatric Medicine.

At present, only about 50 per cent of the graduates of CCPM are able to obtain a residency in an approved program.

CCPM offers seven first year residencies and five second year residencies, both in podiatric surgery. These programs include full-time rotations to the U.S.P.H.S. Hospital, San Francisco; V.A. Hospital, San Francisco; Presbyterian Medical Center, San Francisco; and Highland General Hospital, Oakland.

At a meeting with a legislative committee the lobbyist for the State Medical Society asked a very perceptive question. He said, "Granted your course of study is equated to that of medicine, but what about the quality of your programs?" This was positive communication! The courses are taught by faculty members who are board-certified or board-eligible in the specialties and sub-specialties of internal medicine, dermatology, neurology, general surgery, radiology, anesthesiology, endocrinology, rheumatology, clinical pharmacology and pathology. A typical faculty may consist of 23 full-time members plus 71 who are part-time; 38 are D.P.M.'s, 5 are Ph.D. and 27 are M.D.'s. A full-time basic sciences faculty, holding the degree of Ph.D., represent the fields of anatomy, biochemistry, pharmacology, microbiology, immunology and physiology. Many of the faculty also teach at local medical schools.

Patients are covered for services rendered by podiatrists under Titles 18 and 19. Under the social security act as amended the term "physician" includes the licensed doctor of podiatric medicine. All insurance carriers including C.M.S. and workmen's compensation cover podiatric surgical and radiologic services.

Podiatrists in office practice maintain a well equipped physical plant and employ medical secretaries, receptionists and as many as five podiatric assistants in a busy office. A surgical suite for outpatient ambulatory surgery is essential and recovery rooms are optional.

In a good general practice a podiatrist performs appropriate physical examinations and takes complete case histories. In the general practice of podiatry as in the general practice of medicine the practitioner performs some surgery and is involved with various injection techniques and physical modalities. He also uses protective shields, pads, corrective orthotics and compensatory appliances. He performs X-ray examinations, and refers to clinical laboratories for blood, urine and chemical analysis. His patients are given a comprehensive podiatric physical examination and the various bodily systems are evaluated as to their relationship to the foot complaint. The podiatrist serves medicine as a consultant and by tradition recognizes the key role of the doctor of medicine whom he consults as a generalist or medical specialist.

The Accreditation Manual for Hospitals of the Joint Commission on Accreditation of Hospitals (1970), updated (1973) provides the protocol for establishing meaningful hospital privileges for podiatrists.

Alfred S. Frobese, M.D., Chief-of-Staff, and Director of the Surgical Division, Abington Memorial Hospital, in a discussion of "Podiatry Service in a Suburban Hospital—A Three Year Review," had this to say, "In short, our experience with a structured podiatric service with inpatient and outpatient privileges, represents an advance in health care and where today's well trained podiatrist is available, a community hospital should find little, if any, problem in developing such a section. A service of this type should prove advantageous to both."

Lawrence J. Rossi, M.D., Founder and Medical Director of the Hopedale Medical Complex states that "Podiatry has proved to me and our medical staff that it belongs on the total health care team. Our resident training program is contributing to this goal by training podiatrists in hospital procedure, protocol and total patient care." In 1971 over 3,560 foot surgical procedures were performed at the Hopedale Medical Complex.

The Appeals and Control Commission of the American Podiatry Association has a very effective peer review committee in Connecticut. We are proud of the manner in which it assumes its responsibilities to the public and the professions.

Our Code of Ethics is used as model by both podiatry and medical societies across the country.

The American Public Health Association has recognized the importance of podiatric services to the public's health and has formally accepted a section on "Podiatric Health."

Podiatry has contributed to the literature of medicine in many ways. At least two recently published books, "Clinical Foot Roentgenology" and "Podiatric Medicine" have been written by a Connecticut podiatrist. Several new medical books have chapters written by podiatrists and most new literature pertaining to foot disease will reference work performed by podiatrists. Symposia on sophisticated surgical techniques have been edited and published in book form. We invite you to study and review our literature and welcome constructive criticism.

In summary what does all of this mean? The professions of podiatry and medicine must face each other with a complete cooperative understanding and appreciation of our frailties, problems and our virtues. I believe that this philosophy must be based on an inward perception and external awareness. This inward perception is a look at ourselves as individual practicing members of important and essential professions. The external awareness is the long view of the relationship of medicine and podiatry to the public we serve. There is no limit to the opportunities for service by the educated and scientifically trained. Podiatrists are established as physicians of the foot and look toward general medicine for help in pursuing a course that will prove more meaningful to the community. Podiatry and medicine have a long history of cooperative effort in serving the health needs of the nation, and we envision an expansion of this relationship. With the emergence of academic health centers for combined educational thrusts we see an opportunity for closer liaison with medicine.

Our successful and rapid growth as a profession has been based on the recognition of our obligations to society. We have tried to demonstrate in a dignified, professional and effective manner that podiatry accepts the responsibility as guardian of the foot health of the nation. We solicit your support and recommend that a liaison committee be established between our professions to allow for a cooperative maximum contribution to the health of individuals and the vast public we serve.

The great French Marshall Lyautey once asked his gardener to plant a tree. The gardener objected that the tree was slow growing and would not reach maturity for a hundred years. The Marshall replied, "In that case there is no time to lose; plant it this afternoon."

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The Myth of the Dichotomy of Expressive and Receptive Aphasia

Robert J. Duffy, Ph.D.

ABSTRACT—In his examination of the stroke patient with aphasia there is a tendency for the physician to overestimate the verbal comprehension ability of the patient and conclude that he is "an expressive aphasic but understands everything said to him." When the patient is then evaluated by the speech pathologist such observations are rarely confirmed. Three reasons for the discrepancy between the observations of the physician and the speech pathologist are discussed. Included is a discussion of the nature of aphasia and a review of the research data bearing on the false dichotomization of aphasia into "expressive" and "receptive" disorders.

A common observation seen in the report of the medical examination of the stroke patient with aphasia is, "this patient has expressive aphasia but understands everything said to him." This comment by the examining physician suggests that only speech is disturbed and that the patient's auditory comprehension is normal. It implies a dichotomy between expressive and receptive language modalities, i.e. that a patient can be *either* a "receptive" *or* an "expressive" aphasic; and, it often further assumes that cerebral damage can produce isolated impairment of single language systems such as speech, auditory comprehension, reading and writing. However, when aphasic patients are tested and evaluated by the speech pathologist, it is rarely (if ever) the case that only one aspect of language functioning is found to be impaired. What is usually observed is that all language modalities are impaired and to about the same degree.

There are at least three common reasons for the discrepancy between the physician's observation and the speech pathologist's evaluation: (1) failure to differentiate between aphasic and nonaphasic communication disorders; (2) incomplete or inappropriate examination; or, (3) the mental set or orientation of the examiner which disposes him to perceive isolated deficits. Each of these factors will be discussed in detail.

Aphasia: Differential Diagnosis

One common reason for the discrepancy between the reports of the medical examiner and the speech pathologist is a nosologic and semantic one. It is a common practice in medicine to use the term "aphasia" generically to cover a wide variety of verbal disorders associated with both neurologic and nonneurologic lesions. Thus, the physician may label as "aphasia" various verbal disorders reflecting a variety of motor, sensory, perceptual, intellectual or emotional dysfunctions caused by cerebral and other lesions. Therefore, when the physician does accurately observe a patient whose verbal comprehension is intact and whose speech is very disturbed, he is probably observing a "dysarthric" or "apractic" patient with lesions in the motor system, but labels him "aphasic," referring to the fact that he has a verbal deficit probably of neurologic origin.

The speech pathologist uses the term "aphasia" to identify a very specific type of disturbance of the symbolic *language* processes and excludes other types of verbal disturbances from this diagnostic category. Therefore, the pathological communication which the physician describes as "aphasia" may not be the same clinical behavior which the speech pathologist so labels. This difference in the use of diagnostic labels may account for some of the discrepancy between the observations made by the physician and the speech pathologist. Obviously there needs to be precise identification of aphasic and the various nonaphasic verbal disorders because they are quite different in nature, and have differing implications for cerebral localization and clinical treatment and prognoses.

Aphasia, as an impairment of the language process, means that there are deficits in the patient's use of both vocabulary and the grammatical rules which we use to appropriately order words and express linguistic features such as number, tense, gender, interrogation, etc. . Since there is only a single language code which underlies our specific behaviors of speaking, comprehending, reading and writing, it is reasonable to expect that lesions in the language processing areas of the brain will be reflected in impaired functioning in all four language modalities. (For a more detailed discussion of aphasia as a language disorder see Duffy, 1972; Schuell, 1964; and Schuell, 1974.) This assertion of

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multimodality impairment of language behaviors in aphasia is overwhelmingly supported by experimental data.

All studies which have used large samples of clinical aphasic patients, and which have employed objective and comprehensive measures of all four language modalities, have failed to support the claim that language modalities can be independently impaired in aphasia. The specific studies referred to and the numbers of aphasic subjects are: Head, 26 (1925); Weisenburg and McBride, 60 (1935); Wepman, 68 (1951); Schuell, et al., 158 (1964); Porch, 150 (1967). The most recent study is that of Smith (1972) who reported on 126 carefully examined aphasics; he presents the following observation:

> Despite Geschwind's (1970) claim that the so called "classical" syndromes of Broca's motor, Wernicke's sensory and conduction, and other anatomically based classifications of aphasia have been 'confirmed repeatedly,' there has not been a single reported study based on objective measures of all four language components that supported the earlier 'classical' differentiation of aphasia syndromes. (p. 54).

In addition to the research studies cited, the presence of multimodality deficits in aphasia can be readily observed in the routine clinical evaluations of the speech pathologist.

Examination Procedures

A second explanation as to why an aphasic patient might erroneously be described as "understanding everything said to him" is the manner of the examination. Generally, during the physical examination the questions and requests addressed to the patient are minimal, simple and often accompanied by situational and other nonverbal cues and do not really test his *verbal* comprehension extensively or exclusively. A common test of comprehension in these circumstances is to ask the patient "yes/no" types of questions (because of his limited speech) to which he can merely nod his reply—and have 50/50 chance of being correct even if he comprehends nothing. Added to this is the fact that most aphasics do comprehend some speech, picking up a word here and there which they may combine with nonverbal cues. Thus the alert and responsive aphasic can often give enough appropriate replies under these circumstances to give the casual and unwary examiner the impression that he does indeed comprehend "everything." Schuell, Jenkins and Pabon (1964, p. 21) describe the situation well in the following statement:

> The report, 'He understood everything that was said,' occurred again and again in the protocols of early investigators. Somehow or other, that is something people always say about aphasic patients, particularly when they have no speech. It is said, again and again, about patients who cannot follow directions as simple as "Put the spoon in the cup." Patients with little or no speech are usually highly motivated to communicate and to perform well. They frequently respond appropriately by making maximal use of visual cues, situational cues, and occasional words they grasp. They observe the social amenities, smile and appear responsive when spoken to. Since they have little or no speech they tend not to give themselves away when they misunderstand, as hard-of-hearing individuals frequently do. Sometimes when the patient makes an obvious error, the speaking person ascribes it to his own difficulty communicating with the aphasic patient. This is a very curious phenomenon.

Ancient or Traditional Beliefs

A subtle, but nonetheless real, reason for the tendency to observe isolated or dichotomous problems in expressive and receptive language performances is the effect of the preconception of the examiner on his perceptions. The belief in the clinical reality of "expressive aphasia" and "receptive aphasia" was strongly espoused by prestigious clinicians in the pioneering stages of the study of cerebral localization and language disturbances during the 1860's and 1870's. Despite the accumulated experimental evidence to the contrary, textbooks and clinical training continue to perpetuate the myth of the dichotomy of expressive and receptive aphasia and thereby predispose the practitioner to perceive patients "who has expressive aphasia but understands everything said to him." This conclusion is particularly likely when combined with hasty or incomplete examination procedures. Over four decades ago, following the completion of their extensive and classical study of aphasia, Weisenburg and McBride (1935, p. 1) offered a warning about the "influence of ancient and traditional beliefs" which continues to have relevance for clinicians today. They wrote:

> One of the immense handicaps in the study of aphasia is the weight of ancient or traditional beliefs. To most neurologists the assertion that language disturbances are incapable of division into motor or sensory aphasia and that such terms as 'agraphia,' 'alexia,' and 'word-deafness' are convenient names which have crept into the literature but cannot be demonstrated as 'pure'

> disorders, brings about an antagonistic reaction, for even neurologists and psychiatrists dislike having their time-honored conceptions uprooted, with the additional prospect of having to learn new test methods for newer classifications. . . .
>
> Until recently most writers on the subject have been interested in the establishment of areas of the brain, lesions in which either produce definite types of aphasia or control certain activities relative to speech. Enough will be said to show that the test methods of the older investigators do not bear close investigation. And the same thing can be said of many of the moderns. Yet it is on such grounds that clinical types of aphasia have been established. Indeed, as in many subjects, various types of disorders have been predicted on purely theoretical grounds; given certain premises on cerebral localization it is easy to describe hypothetical syndromes, and such types have crept into the literature, never either proved or disproved, but accepted by subsequent writers as definite facts.

Summary

The purpose of the present article is not simply to be critical or to review old controversies, but to clarify a current clinical problem in the evaluation of the aphasic patient. Frequently there are differences and discrepancies between the conclusions reached by the physician and by the speech pathologist regarding the nature and extent of the patient's communication problems. Often the physician concludes from his examination of the patient that he has "expressive aphasia but understands everything said to him." Yet typically, when an objective and extensive examination of the patient's communication abilities is made by the speech pathologist, it is found that all language modalities are impaired to approximately the same degree. This discrepancy between observations appears to be the result of different concepts about the nature of aphasia, or incomplete or inappropriate examination procedures possibly combined with a strong belief in the existence of a dichotomy between "expressive" and "respective" language abilities.

Aphasia and other types of communication disorders are complex and their complete description and differential diagnosis may require extensive evaluation and testing by a trained and experienced specialist such as the speech pathologist. As a practical suggestion and concluding remark, I would strongly urge that the physician who does not have the training and opportunity to do a thorough evaluation should refrain from drawing conclusions about the specific nature and extent of the patient's communication deficits; and, that when it is necessary to identify the specific nature and extent of the patient's deficits, a referral should be made to the speech pathologist for a complete evaluation of the problem.

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"For when was honey ever made with one bee in the hive"...

Thomas Hood, *The Last Man*

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Human Research in Connecticut Prisons

Thomas A. DeRiemer

What issue today can stir more debate than the question of the propriety of testing bio-medical products in an incarcerated population? How often do we hear the question: "How can freedom of choice and informed consent ever truly exist in a prison?"

The physicians, pharmacists, scientists, lawyers, administrators, other professionals and lay persons associated with the Correction Research Advisory Committee of the Connecticut Department of Correction, know the issue is explosive but not impossible to deal with. Their first charge, under departmental directive, is to protect the health and safety of all subjects—to reject any proposed study where questions of harm to participants are not answered to fail-safe standards.

As a free society we naturally have been concerned with medical experimentation on humans in an institutional environment, whether it involved "volunteers," medical patients, the poor, or those incarcerated.

Are "volunteers" being taken advantage of or treated as "guinea pigs?" Does the public good that might result from experimentation outweigh the potential harms to the individual? If there need be testing in humans, where else can the tester turn?

In recent months medical experimentation in correctional facilities has received a major focus of attention, both within correctional circles and with the general public. In Connecticut there has never been a fatality attributable to any form of testing in the correctional setting. To be more exacting, no test effects of an injurious, damaging or harmful nature have ever been reported beyond the normal follow-up period in the original study design as approved by the RAC.

We are all aware that a number of concerned citizen groups have been formed since Attica. A report that the Public Health Service failed to treat a "control" group of poor blacks with syphilis as a part of an experiment, despite the advent of penicillin, has brought considerable public attention to the area of medical experimentation.

The American Correctional Association recently stepped up its effort for uniform rules and regulations. A committee appointed by ACA put forth a "Protocol for Medical Experimentation and Pharmaceutical Testing" in February, 1972. This issue was also hotly debated in the Medical Practices Committee meeting during the annual convention in Pittsburgh in August, 1972. Connecticut was an important contributor to those discussions.

The Connecticut Department of Correction, ACA and FDA guidelines regarding inmate safety are within the scope of responsibilities assigned to the Research Advisory Committee (RAC).

Department Started in 1967

Briefly the Connecticut Department of Correction was established in 1967 and became operative in 1968, administering all adult correctional facilities, including jails and parole.

Responding to questions and concerns at the time, the commissioner shortly after his appointment by Governor Meskill, declared a moratorium on drug experimentation which remained in effect for several months.

Meanwhile the commissioner received literally hundreds of letters from inmates asking that experimentation continue. Not one inmate letter was in opposition to bio-medical testing. The RAC was established by directive on 9-8-71 to oversee all research activities (bio-medical and sociologial) of the department. (The directive underwent major revisions as recently as May 20, 1974.)

Lacking formal guidelines, and unable to find any reference in available literature to previous organized efforts in this area, the RAC set out to establish a comprehensive guideline to sociological and medical research conducted in a correctional environment.

After a great deal of soul-searching and trial and error, the RAC has developed a viable set of regulations which serve to screen, direct and catalog all research within corrections. A fee schedule guarantees a fair direct payment to inmate volunteers, a secondary financial benefit to the entire inmate population and the recovery of indirect costs to the State.

Private funds were used to commission a research project to determine whether this type of medical experimentation is helpful or harmful to overall rehabilitative goals.

Research Advisory Committee

Early in its developmental stages the Connecticut Research Advisory Committee was a multi-disciplinary group.

The review process still continues to demand many skills. In May, 1974, the single RAC which had

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four subcommittees: Phase I, Phase II, Psychiatric/Psychological and Social/Political, was reorganized along recent HEW suggestions.

Corrections has formed an alliance with the University of Connecticut Health Center. Medical/technical studies are first submitted to the UCONN Health Center Bio-Medical Review Subcommittee. The subcommittee includes Dr. Robert Volle, Head, Department of Pharmacology, and a Professor of Pharmacology, a Psychiatrist, the head of the Department of Nephrology, a Professor of Laboratory, a Professor of Medicine and the Director of Drug Information of the Department of Pharmacy—all from UCONN Health Center plus the corrections Director of Research, Chief of Medical Services and Chief Pharmacist. Medical consultants assist as needed. The new organization assures that medical/technical skills are not expended on a procedural or sociological debate—thus introducing an economy of effort.

If a bio-medical product is approved by the Health Center group, or if the protocol does not have a medical facet, then it is sent to a second RAC unit known as the Organizational Review Subcommittee.

The ORS is composed of sociologists, psychologists, lawyers, business managers, clergy, educators, trainers and other administrative types. A study which has been passed by both subcommittees and has approval of the Warden and Chief Corrections physician, is sent to the Commissioner for final approval/disapproval action.

While the Health Center and Organizational Review groups are at work there is a parallel review process underway via the Institutional Protection Committee for the facility where the study may ultimately be conducted. This committee has one or more inmate members and once a study is underway it will function as a consumer watchdog. The groundrules require that a different inmate be assigned to each study. In the event of concurrent studies, he may devote his exclusive interests to only one. It also helps if he does not get too familiar with one drug company's test group.

Committee Functions

1. Every request received by Corrections for the conduct of research of any nature within any institution is presented to the RAC through the chairman, whose primary assignment is Corrections Director of Research. All such requests must conform to the "Format Outline for Bio-medical Protocols."

The RAC chairman or Health Center subcommittee chairman may communicate directly with the Investigator concerning obvious problems, such as incorrect formats. The RAC chairman is responsible for distributing copies of proposals to all RAC members and to affected institution warden prior to regular meetings of the Health Center subcommittee. RAC members must be present at scheduled meetings to vote.

An individual or organization whose protocol has been approved must submit interim and final reports, and copies of any resulting publications. The function of the RAC is not to legitimize good or bad reports but to direct, catalog and correlate results for the good of the department and the welfare of its inmates.

The RAC evaluates each proposal as to design, timeliness, desirability, feasibility and priority. Institution heads are informed of a proposal affecting their facility and the institution head may review the proposal with the committee.

The RAC is responsible for the initial approval of a project and for ongoing monitoring and periodic evaluation of progress, with the option of stopping the project at any time.

2. It is the responsibility of the Commissioner to ensure proper and complete review from both the technical and the broad ethical and moral standpoints. If appropriate personnel are not available from staff or consultants, outside sources or committees are utilized. Such a committee may be a standing committee at a university or at a medical center. Such reviews are in accordance with FDA or other regulations as applicable.

3. The Commissioner retains authority to veto any experimental project, either prior to initiation or during progress, and must take particular cognizance of features of the experimentation that are inappropriate in the correctional setting.

There are clearly many projects which constitute no problem in other settings but because of the nature, risk or ramification are unwise in the correctional setting; for example, any which would involve significant risk of injury. A project involving presumed risk or uncontrollable risk is not allowed.

4. Each volunteer under a pharmaceutical study must be given a full verbal and written explanation compatible with the principle of medical "informed consent" and must execute a signed consent.

The signed consent must include a reasonable review of the project in the text of the consent with a copy given to the volunteer. Documentation must also enumerate and clarify that the full consent procedure was followed.

So much concern surrounds the issue of "informed consent" that a major study of this single ethical issue has been approved. The design of the study was cleared by the Sociological Review subcommittee of the RAC and with private funding is being conducted by three doctoral candidates under the direction of Michael Sheard, M.D., Yale Medical School, and Marvin Reznikoff, RhD, Fordham University.

5. The Commissioner ensures that each volunteer is screened for both physical and emotional preparedness. Pre-screening is presumed to occur during classification and by the physician responsible for medically screening volunteers.

Particular attention is paid to emotional factors, including reasons for volunteering. Professional assistance is sought in the evaluation of borderline volunteers who are being favorably considered.

6. The RAC must carefully evaluate the nature and degree of compensation provided to any and all volunteers and be satisfied that the compensation is compatible with the general welfare of the institution.

Any offer of "good time" reductions to sentences constitutes an unfair inducement. The act of volunteering must not carry with it the expectation of latent benefits and conversely, failure to volunteer must not create the expectation of adverse action.

7. The RAC must ensure that any infringement upon inmate schedules does not compromise ongoing programs or other related correctional activities.

Adequate time is necessary in the inmate's schedule for education, vocational training, recreation, work detail, counseling and related programs. In most instances experimental projects requiring significant amounts of inmate time would, in fact, compromise these basic programs.

8. Even though in many situations a prison population may constitute an unusually satisfactory group for a particular experimental study (there may be a specific need for a population existing under these controlled conditions) the RAC should not be unduly influenced by this need.

The prison population constitutes a readily available group of individuals whose environment can be well identified, described and controlled. Prisoners are usually willing volunteers and may accept minimal compensation. Consequently they are frequently sought for experimental studies. The RAC assures that no one is induced to participate; he does so of his own choosing. No benefits or reward, by way of special privileges or reductions in confinement periods, etc., are allowed by the department.

9. The Nuremberg principles (enumerated at the Nuremberg War Crimes Trial) and the Declaration of Helsinki must be followed with appropriate expansion and other modification by the administration to avoid unreasonable risks.

Compensation for Inmate Volunteer

Perhaps the most time-consuming discussion by the Research Advisory Committee in its formative stages surrounded the development of a reasonable stipend for inmate volunteers, who traditionally have been without bargaining representation. The committee easily agreed that payments should be commensurate (taking into account the special economy of a prison setting) with what a non-inmate volunteer outside of the prison could expect.

No suitable "market" data was available from Connecticut experimental groups nor from similar units in the adjoining northeastern states. The sparse bit of specific fees data showed that inmate volunteers were truly economically exploited. Inmates from the Connecticut system (including representatives on the RAC) universally declared that money was the prime motivation for volunteering—even at unfair rates.

Since market data was wanting, the RAC took aggressive action to catch up with the current economy. All drug companies which had conducted studies within the Connecticut correctional system were listened to at length and while they were protective of their operating overheads, were nonetheless very helpful. In this rate-setting role the committee was likened to levying taxes.

One valuable contribution from the private companies was the use of a "participant" fee for any inmate screened for a study whether or not he was accepted to participate. Participants receive additional flat rate payment from a fee schedule which recognized personal discomfort. Risk is presumed to have been eliminated through the introduction of strict controls on study conduct. Adequate medical safeguards must be imposed where risk is not predeterminable.

Some inmates, for physical, emotional or administrative reasons, are never eligible to participate in studies. In recognition of this institutional characteristic, the RAC levies an "overhead charge" computed at 50% of the total payments to inmate participants. This charge is paid into that institution's general inmate welfare fund and may be spent for items to enhance general institutional conditions not provided for in State budgets.

Institutional operating overhead costs are high and these costs (heat, light, audit expenses) are recovered by the assessment of an overhead charge payable to the State General Fund.

Several important attitudes were delivered by drug houses to our RAC during fee schedule deliberations. One serious issue from the corrections viewpoint was the "fee bargaining" attitude of placing studies where the cheapest price is available.

It takes form in the remark that "if conditions for study are not completely satisfactory then the study will be placed elsewhere, depriving you of some great economic gain." We take the position that there should be universal rates from one state to the next, perhaps adjusted regionally to reflect area markets.

Further, it is apparent that there are drug study jobbers. These medical people contract with sponsoring manufacturers to place studies where the required number of human subjects is available. The more cheaply they can place a study the more dollars they retain for themselves. We see the cost of human volunteers is a negligible part of the total expense of making a drug market-ready by FDA standards.

We also find a tendency to place economic pressures on departmental employees. Certain supportive services have to be provided by departmental physicians, medics, nurses, clerks, custodial personnel and inmate trustees. Even for payments to these employees who support studies in an overtime status and who may therefore be paid directly by the company, ethics suggest that government employees should receive only one paycheck—from the primary employer—and any company payments to corrections employees should be made to the State general operating fund, including all overheads and overtime premiums.

Pharmacological Studies

In submitting a protocol for consideration by the Research Advisory Committee, a statement is made to the effect that "subject to special fees as may be prescribed by the RAC and approved by the Commissioner of Correction, the (name of company) agrees to the Department of Correction fee schedule dated 5/20/74."

No work may commence until financial arrangements have been approved by the commissioner.

The following fee schedule has been established for listed procedures. Items not listed are negotiated on an individual basis.

1. General Fees.

a. A "participation fee" varying from a minimum of $25.00 to a maximum of $75.00 is paid to each inmate who is selected for a given research program following the screening procedures. Where scheduled fees for a study of less than a week would amount to less than $25.00, that is the minimum per subject.

b. In addition to the participation fee the following procedure charges are paid the inmate:

1. Initial blood drawing for laboratory screen or profile—$10.00.
2. All blood specimens after initial screen—$2.50.
3. Urine and fecal specimens—$1.00.
4. 24-hour urine and or fecal specimens—$5.00.
5. B.S.P. (Bromsulphalein Test) 2-3 bloods—$12.50.
6. Glucose Tolerance Test (5 bloods)—$12.50.
7. Spinal puncture—$15.00.
8. EKG—$3.00.
9. Inmates performing clerical duties, a minimum of $10.00—$10.00 per week.
10. Blood donations for research, 1/2 unit (250cc)—$10.00; 1 unit (500cc)—$20.00.

c. Checks are made to Inmate Fund, (Somers) Correctional Institution.

2. An additional payment, equal to 50% of the total paid to inmates for each protocol, is paid to the inmate welfare fund of the institution providing participants. Checks are payable to Inmate Welfare Fund for the institution or center involved.

3. If payment is to be made by the Department of Correction to employees, a fringe benefit direct cost of 30% is added to personal services costs payable by the company. This payment is made to the State of Connecticut.

4. A direct charge of 12% based on payments to inmates exclusive of the amount paid to the general inmate welfare under (2) above. Make check payable to the State of Connecticut.

5. An indirect charge of 6%, based on the total of (3) and (4) above, shall be paid to the State of Connecticut. This represents the value of services furnished by other state agencies such as auditors, personnel, comptroller, treasurer, purchasing division and central office of the Department of Correction. The indirect cost rate will be adjusted yearly.

The commissioner reserves the right to waive any and all fees for a project if he deems it in the best interest of the department and the state.

All fees are subject to change by the department and acceptance of the changes by the study sponsor prior to study initiation. The schedule is viable and undergoes continuing change (generally upwards) as conditions warrant.

This schedule is applicable to all commercial researchers on an equal basis.

Conclusion

One of the major issues the RAC has struggled with since its inception is whether medical research should be allowed. Is it helpful or harmful to our overall rehabilitative goals? A review of the literature reveals no hard data on this subject, merely a handful of subjective narrative reports. Through a grant sponsored by a private source the department has chartered a study titled a "Research Proposal on the Social, Psychological and Attitudinal Implications of Pharmacological Testing in a Correctional Institution."

It is the department's view that there needs to be a considerable amount of study before concluding whether medical experimentation should be encouraged or discouraged in correctional settings.

In summary, Connecticut Corrections has a working model for medical experimentation and pharmaceutical testing. Its fee schedule is put forward as a baseline for fair compensation.

As usual no simple answers have been encountered. Each step taken in Connecticut has been a milestone. The progress achieved in Connecticut is available to others to build on. Needed now are the results of practices and fees in other regions and from this flow of information light can be shown upon some of the remaining gray areas surrounding drug tests in humans.

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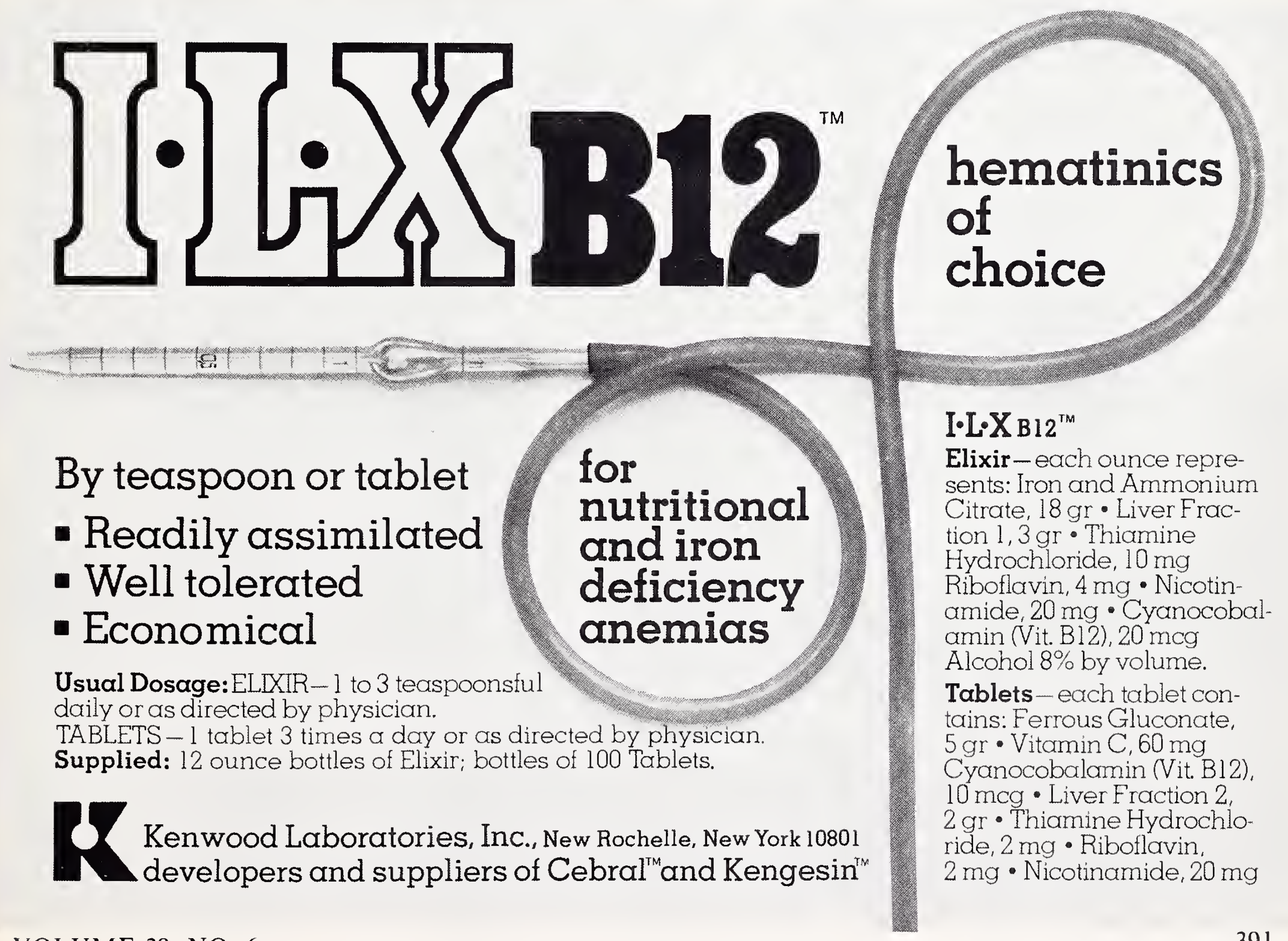

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Continued on page 402

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Precautions: Since varying degrees of urinary hesitancy may be evidenced by elderly males with prostatic hypertrophy, such patients should be advised to micturate at the time of taking the medication.

Overdosage should be avoided in patients severely ill with ulcerative colitis.

Adverse Reactions: Varying degrees of drying of salivary secretions may occur as well as mydriasis and blurred vision. In addition the following adverse reactions have been reported: nervousness, drowsiness, dizziness, insomnia, headache, loss of the sense of taste, nausea, vomiting, constipation, impotence and allergic dermatitis.

Dosage and Administration: The recommended daily dosage for adult oral therapy is one 15-mg. tablet with meals and two at bedtime. Subsequent adjustment to the patient's requirements and tolerance must be made.

How Supplied: Pro-Banthīne is supplied as tablets of 15 and 7.5 mg., as prolonged-acting tablets of 30 mg. and, for parenteral use, as serum-type vials of 30 mg.

SEARLE **Searle & Co.**
San Juan, Puerto Rico 00936

Address medical inquiries to: G. D. Searle & Co.
Medical Department, Box 5110, Chicago, Ill. 60680 481

Stealing a Look at Your Theft Insurance

Most people don't read their policies until after the burglar has gone. We show how to make sure your coverage is adequate and how to tailor it to your needs. *by Jo Degener*

One Thursday last June, after an especially grueling day at her Chicago Tribune typewriter, education writer Connie Lauerman, 27, was looking forward to a quiet evening at home. But when she got to her apartment, she was horrified to find that the wooden door was missing a large chunk around the lock. "At the sight of that door, I got a terrible sinking feeling in the pit of my stomach," she recalls. "I had a sense of almost personal violation: someone had obviously forced his way into my apartment where he didn't belong. I made myself open the door just to see how bad it was inside."

Gone were a three-week-old tape recorder, an expensive camera and some cash. "I found myself getting increasingly angry," she says. "I'd finally gotten to the point in my career where I was getting a little bit ahead on money and I could buy some of the things I'd always wanted. Then along comes someone and takes it all. The only good news was that the thief was pretty neat."

Ms. Lauerman was insured under a tenants policy that covered theft as well as fire and other perils. Like many insured theft victims, she followed her report to the police with a frantic call to her agent to see if she was completely covered for the burglary. She was not. While the rest of her policy insured her for any loss over $50, the section on theft carried a deductible of $250; she would have to pay that part of the loss herself. The call to the agent was the first time she remembers hearing about the special theft deductible. "Until you're faced with a burglary," she says, "you don't look closely at the terms of a policy. You accept them, you pay your premiums, and you hope you'll get something in case there's a loss."

All too often it's only post-heist that a policyholder discovers, for example, that a standard policy may have unrealistically low limits on coverage for valuable property like cash, furs and jewels. Also, policyholders often don't know in advance which types of property require documented proof of value. And in these days of superinflation, probably the most common problem of all is insurance coverage that has become inadequate because the insured property has increased in value tremendously—particularly the highly expensive and easily transportable items that thieves like best. In just the past two years, for instance, the value of gold jewelry has more than doubled, the prices of rubies, sapphires and emeralds have gone up 70%, and the average new watch now sells for 45% more.

To make sure you're adequately protected against theft in advance, you first have to calculate how much coverage you need. Then you need to find out in some detail what standard theft insurance does—and does not—cover. Finally, you should explore some of the extras that can tailor your protection more snugly to your own needs.

The Proof of the Hasselblad

Most insurance experts strongly advise taking a complete inventory of your possessions and reviewing your theft insurance coverage annually; this is especially good advice for a young family that is acquiring a significant amount of new belongings each year. An inventory helps you figure out how much coverage you need, and it will also provide a useful record of your possessions should you ever have to file and substantiate a claim. All companies require written notice of a loss, ideally with receipts or other evidence of value and ownership. An inventory isn't as ironclad as a receipt, but it can help. Even without a receipt or an inventory, most companies will often accept a policyholder's word. One insurance company spokesman explains: "If the claim is for the loss of an average camera and the guy says he paid cash, we'll take it on faith. It's when someone in a $75-a-month apartment claims the theft of a Hasselblad that we'd question it."

An insurance company bases its settlements on the actual cash value of a stolen item—defined as the cost of replacing it at today's price, minus an allowance for depreciation. To illustrate the calculation: a set of stereo components bought in April 1973 was carted off by burglars last winter from a

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vacation house in New York's Catskill Mountains. When new, the system cost $920. In January 1974 the same system was priced at $1,078—a 17.3% increase in nine months. The insurance company started with the replacement cost of $1,078 and subtracted 10%, or $108, for one year's depreciation. From the result, $970, they next subtracted the deductible of $50. The policyholder got $920—by coincidence, just what he'd originally paid.

When you're ready to start your inventory, go through your house listing all your possessions, wherever possible with the dates of purchase, prices and serial numbers. You can calculate depreciation after you've completed the inventory. In the case of gifts and heirlooms, list the date of acquisition and any other identifying information.

An appraisal by a specialist familiar with the market is the best way to determine the value of jewelry, antiques, paintings, collections and art objects in general. A letter of appraisal is also the best proof of value should there ever be a claim. For appraisals on jewelry, try your local jeweler; for antiques, you could ask a local antiques dealer with a good reputation. To find specialists in other items, a large department store would be a good place to inquire. The cost of appraisals generally depends on the amount of research involved and whether you can bring the object to the appraiser. A jeweler might charge $10 to appraise an ordinary diamond at his store; it can cost over $300 to have an appraiser spend a day evaluating a houseful of possessions. For more information on how to find and appraise appraisers, as well as on how to prepare an inventory, see "What Have You Got to Lose?" *(Money,* December 1972). If you have nothing you want to insure separately and don't want to bother consulting an appraiser, taking snapshots of particularly valuable items is a good alternative method of establishing proof of ownership and value.

What's Covered and What Isn't

Here is some basic information on the theft coverage most insurers offer under their standard policies —and how you can vary it:

Basic theft coverage. Almost all theft insurance is sold as part of a package that offers the house owner or renter protection against a variety of perils; fire, windstorm and theft are the chief causes of loss. The packages are known as homeowners and tenants policies.

For those who own their own houses, there are four packages available, usually called HO (for homeowner) -1, -2, -3 and -5. The first three are virtually identical in theft coverage. HO-5 is much broader, but its premium—which can run 85% higher than that for HO-1, the cheapest package—puts it beyond the reach of most families; hardly anybody needs the extremely broad protection it offers, which includes unlimited coverage of all your property anywhere you take it. HO-2 is the most widely sold homeowner package. Renters have less choice. Most companies offer only one tenants policy, the HO-4. Coverage is identical to that of an HO-2 policy, although naturally the tenant package offers no insurance on the building. The amount of theft coverage is the same as the total amount of the policy.

The amount of theft coverage in homeowners policies is based on the insurance on the dwelling. Most companies require that you insure for at least 80% of the cost of rebuilding the house. (It's not necessary to have 100% coverage since the foundation of the house, which typically accounts for some 20% of the construction cost, is unlikely to be destroyed.) On a $50,000 house, therefore, you'd be insured for $40,000. In addition, standard coverage for the contents of a house is 50% of the 80%, or $20,000. You can go as high on contents coverage as you like; the minimum that most companies allow is 40% of dwelling coverage.

In your own house or apartment, or in any building on your home turf, such as a tool shed, you're insured against any theft. You're also covered for any of your property in a warehouse or safe-deposit box, for anything you rent, like a camera, and for the possessions of your guests. Boats and trailers are covered if they're stolen while being kept at your main property. It makes no difference whether the thief uses force or simply comes in through an open door, and it makes no difference whether or not the theft is observed. There simply has to be a strong likelihood that a theft has taken place. Consider the following claim settled by State Farm last October: A young couple had been taking a bath together at their house in central Illinois. When they emerged from the tub, their watches, which they had left outside the bathroom, were gone. Since the screen on the porch was ripped open, it seemed likely that someone had just entered and helped himself. The wife explained in the claim: "We were too preoccupied to hear anything." That was good enough for State Farm, which paid the claim within three days.

Coverage off the premises. Away from your residence, most standard policies cover you for up to 10% of your total insurance on contents, or $1,000, whichever is more. INA's policies are an exception; they offer 100% coverage anywhere—except at a second house you own or rent year round. (Second residences normally require separate coverage, though it's often available at a discount if you buy it from the company that insures your principal dwelling.) Thefts from a car, trailer or boat—no matter where they're located—are also covered as long as the item is filched from a locked compartment. In the New York metropolitan area, there's no off-premises coverage unless you pay a slightly higher premium.

Limits to coverage. Under the standard policy, you cannot recover more than $500 for a theft of furs and jewels. (In metropolitan New York, the limit is $250.) The maximum recovery for stolen coins, cash or bullion is $100; for manuscripts it's $1,000 and for securities $500. For boats and trailers, there's a $500 maximum. There's no coverage at all for fish and animals or for a precious stone that's stolen from its setting (because it's hard to establish that the stone didn't simply fall out).

Deductibles. In most states, insurance companies offer flat deductibles of $50, $100, $250 or $500. Switching to a higher deductible can mean big savings on premiums—often enough to permit greater coverage without a boost in premium rates. In some places, it's possible to get 20% more coverage with no increase in premiums by switching from a $100 to a $500 deductible. Just switching from a $50 deductible to a $100 deductible can get you a 10% credit on your premiums. If you're interested in switching, remember that you can generally take a federal tax deduction on a loss over $100 that's not covered by insurance.

The standard homeowners or tenants policy normally has a single deductible. Still, as Ms. Lauerman of the Chicago Tribune found, there is sometimes a separate, higher deductible on the theft portion. A $250 deductible on theft with a $50 deductible on the remainder of the policy can save up to 5% in premiums.

Endorsements. Once you've decided on your basic coverage, there are a number of ways you can fit it more precisely to your requirements. If you need more insurance on the contents of your house, but don't need higher insurance on the dwelling, an endorsement, or amendment, is the technique to use. All companies will sell you such additional contents coverage, but even when you increase the total you're subject to the same basic limitations as before. Endorsements can also be used to expand the range of items covered. Also, almost all companies may let you raise the limits on coverage of securities to $1,000 and of cash to $500. The securities extension costs about $3.50 per $100 of insurance; the cash extension costs about $5.50 per $100.

A unique and useful endorsement, sold by the St. Paul Fire & Marine Co. for about 10% in additional premiums, extends the coverage of contents loss to the full replacement cost—with no deduction for depreciation, except where the property has already depreciated to 25% or less of its replacement cost.

For those particularly concerned about inflation, quite a few companies sell "inflation guard" endorsements. Under the most common plans, you get 1% more coverage each quarter on the value of your house for an additional 1½% a year in premiums. That automatically increases contents coverage as well. Inflation has lately been running more than 14% a year, but that 4% annual increase in coverage is better than nothing.

Continental and State Farm, among others, offer a more substantial plan. They tie increases in coverage to increases in the construction cost index—which was up 9% in 1973 and 13% in the first nine months of 1974. Under those plans, as well as a similar one sold by Travelers, you pay nothing extra until your next annual premium reflects the added coverage.

Floaters. Another very important way to get the special theft protection you may need is to buy a "floater," a separate policy that covers possessions for their full appraised value anywhere in the world. It follows you—"floats" with you—wherever you go. The insured article must be formally appraised, but in addition to getting the full value of the article if it's stolen, you're covered for all risks, including breakage and simple loss resulting from your own carelessness. It's the most complete property protection you can buy. You can get the same full coverage for all your property with an HO-5 policy, but the advantage of the individual floater is that you can get it on a selective basis, without paying for insurance that you don't need.

Just about anything can be insured with a floater. If there's no rate on the books for the property you want to cover, the company will negotiate with you. State Farm has a $1,500 floater policy on a llama ($30 a year), a $3,000 floater on a collection of beer cans ($75) and a $3,500 floater on a collection of antique barbed wire ($61). More typical floaters cover cameras (about $1.30 per $100 of coverage, at INA's rates for Denver), furs (48¢ per $100), jewelry (about $1.25 per $100) and art objects (about 23¢ per $100). Floaters on art objects cost least because pictures and antiques tend to be bulky, and thus unattractive to unsophisticated thieves.

A few companies also offer a kind of hybrid coverage for unappraised valuables. The maximum amount you can insure for ranges from about $1,500 to around $4,000, and you can include any combination of jewelry, furs and watches under the policy. The premium is likely to fall between the rates for furs and for jewelry.

VARIATIONS ON A PREMIUM

LOCATION AND INSURER	*HOMEOWNERS POLICY ($50,000 dwelling)*		*TENANTS POLICY*		*$3,000 JEWELRY FLOATER*
	with contents coverage of:		*with contents coverage of:*		
	$20,000	*$30,000*	*$20,000*	*$30,000*	
QUEENS					
Crum & Forster	$238	$258	$117	$161	$84
INA	264	284	129	172	76
State Farm	214	232	118	154	84
DENVER					
Crum & Forster	208	228	75	105	45
INA	194	219	89	124	38
State Farm	145	163	54	64	41
DES MOINES					
Crum & Forster	173	193	78	118	27
INA	151	176	116	161	26
State Farm	131	149	58	78	27

In this table of annual premiums, the standard homeowners policy costs more than an apartment dweller's because the homeowner is buying insurance on both house and contents. Where such other risks as fire and windstorms are roughly equal, as they are in the three urban areas above, premiums will vary mostly with the company's past experience with theft claims under each type of policy; a place that has a relatively high crime rate, like Queens, in New York City, will tend to have higher premiums than, say, Des Moines. Premiums for separate "floater" coverage of jewelry also reflect crime rates. *Money* chose three representative insurers that use differing methods to set rates.

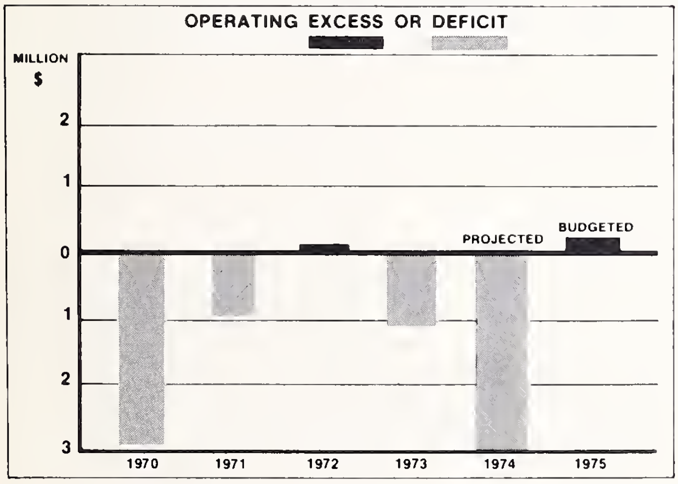
The Last Resort

Until a couple of years ago, finding—and keeping—theft insurance was a major problem for many homeowners and tenants in areas with high crime rates. These days the problem is choosing among all the different kinds of coverage available. Nevertheless, some people still have difficulty getting insurance because they live in a high-crime neighborhood or have made frequent claims. Fortunately, they can get federally subsidized crime insurance in 14 states and the District of Columbia. Up to $10,000 worth of federal insurance is available for premiums ranging from $4 to $8 per $1,000 of coverage, depending on the location. (For more information, write Federal Crime Insurance, P.O. Box 41033, Washington, D.C. 20014.) Federal insurance requires you to install high-security locks if you don't already have them. Also, theft away from your premises must be observed by you in order to be covered, and you're not covered against theft if there's no sign of forced entry. One New York bachelor who could only get federal insurance decided to post a laconic notice: THIEVES: PLEASE DON'T PICK THE LOCK, BREAK DOWN THE DOOR.

Special Report on the AMA's Financial Situation

What Exactly is the Crisis?

How did the world's largest medical and professional organization get into this crisis? Very simply, AMA revenues have become inadequate to meet operating expenses. The Association has operated at a deficit in four out of the past five years (See graph below), and reserves are insufficient to cover an additional deficit. These deficits have occurred despite concentrated efforts to hold the line by slashing staff and other costs in the past five years. Without additional revenue, the AMA will be forced to cut back even further and drop many needed activities vitally important to the profession and the public.



Why the Deficits?

The principal reason is the same one that has affected virtually every individual, business, and organization in this country—inflation. You, in your own practice, are well aware of inflation's impact on your operating costs.

Your AMA is no different. But there have been three other factors unique to the AMA that have further aggravated its financial problems.

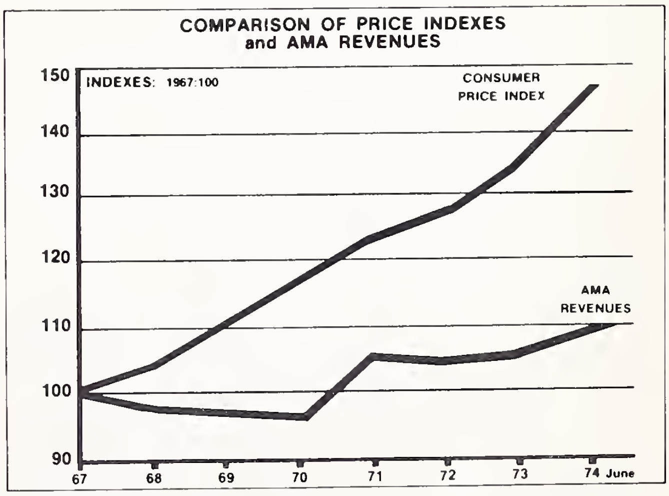
- In the past five years, your AMA House of Delegates has approved dozens of new programs to keep medicine's voice strong in a society that becomes more complex by the day. They have approved publications to keep you better informed on socioeconomic matters and on the Washington legislative scene. Each program, each publication, each action calls for a greater expenditure of money and staff.
- Each time Congress acts or proposes to act, your AMA must speak out for physicians and patients. The number of health and medical bills before Congress—now nearly 3,000— increases each year.
- Membership dues, AMA's main source of income, are fixed. The last dues increase was approved by the House of Delegates in 1970. The AMA has and will continue to make a concentrated effort to live within our means. Less important activities have been reduced or eliminated. New cutbacks alone will not entirely compensate for inflation.

Inflation's Impact on the AMA

Here are just a few examples of the increases in fixed costs since 1971:

- Paper costs—UP 45%
- Printing costs—UP 18%
- Postage—UP 23%, and going up another 30% this year.
- Fuel to heat and light the headquarters—UP 66.6% ($53,524 to $89,189)
- AMA's real estate taxes are in excess of one-half million dollars ($513,000.00).

The graph below will give you a pretty fair idea of the growing gap between AMA revenue and price increases.



Report of the AMA Board of Trustees

What Your AMA Has Done To Cut Costs.

Because of the severity of the revenue-cost squeeze, the AMA has been forced to take many drastic and difficult cost-cutting measures. Among them have been:

1. Reduced staff 10% (from 1,030 to 928 as of December 31, 1974).
2. Closed 8 of the 12 AMA Regional Offices.
3. Eliminated 4 entire departments.
4. Eliminated overtime, outside help, and complimentary printed materials.
5. Suspended hiring for vacant positions.
6. Terminated the publication of many booklets and pamphlets.
7. Cut mailing costs of publications by in-house handling rather than outside.
8. Decreased AMA travel $1,105,000 from original budget.
9. Reduced miscellaneous printed materials 85%.
10. Ended complimentary distribution of *American Medical News* to 125,000 non-members.
11. Cut back the number and use of phones.
12. Cancelled 11 newsletters and suspended many others.
13 Imposed registration fees on all AMA meetings.
14. Cut back on the use of copying machines.
15. Lowered quality of paper purchased.
16. Cancelled Public Affairs Workshop.

Overall, the AMA's approved 1975 budget is reduced over 15.2% from the original budget for 1975. Further cuts will be made within the next few months.

The $60 Assessment (Tax deductible like your dues).

With the additional revenue generated by the assessment *and* the reductions already made, the AMA will have sufficient funds to get through 1975 with a narrowly -balanced budget and to begin rebuilding its reserves. The assessment is essential if the AMA is to be in a viable financial position to meet present and future challenges to the profession. Among the AMA's top priorities for 1975 are:

- A broad attack on the problems of *professional liability* and *rising malpractice insurance premiums.*
- Strengthening our efforts to have effective impact on all *national health legislation* and have a strong voice in the direction of any national health insurance program.
- Opposition to government efforts to reinstate mandatory *controls on physician's fees.*
- Expansion and improvement of continuing *medical education programs.*
- Modification of health planning legislation which would establish a highly-structured, public utility type regulatory system to control the health care sector.
- Continuing opposition to any health manpower legislation which calls for federal licensure or relicensure, conscription of medical students or national control of medical residencies.

Does the AMA Deserve Your Support?

Maybe that's the question you're asking now. What *has* the AMA done for you lately? For starters, there's one thing that will have a very significant impact on your future financial well-being. Through AMA efforts, the Keogh law was modified to allow increased annual contributions to your retirement plan of 15% of earned income or $7,500 whichever is less. On the following page you'll find a brief summary of some of the other ways the AMA serves you. It just might surprise you.

The AMA Urgently Needs Your Help.

Please send your $60 check today.

What's the AMA done for you lately?

Here are some of the things that haven't happened to you and the profession because the AMA went to bat for you:

- Precertification of hospital admissions
- Kennedy-Griffiths NHI Plan and others you couldn't live with
- Discriminatory controls on physician fees "No Phase V"
- Sweeping Federal HMO grants
- Public utility control of your practice
- National re-licensure
- Unrealistic restrictions on physician discretion in prescribing drugs
- Mandatory government service for all medical school graduates
- Premature HEW establishment of consumer-run program review teams for Medicare and Medicaid

Here are some of the key benefits and services AMA membership provides:

- Insurance programs that provide broader coverage at a cost lower than you can find anywhere.
  (Excess Major Medical Program, Group Term Life Insurance, Supplemental "In Hospital" Insurance, Accidental Death & Dismemberment Plan, Disability Income Insurance.)
- AMA Members Retirement Fund
- The nation's largest physician placement service
- Leading scientific publications

- Authoritative legal information and guidelines on every aspect of the practice of medicine
- Professional management information and guides to increase the productivity and profitability of your practice
- The research resources of one of the nation's greatest medical libraries
- The most comprehensive scientific programming available anywhere at the AMA Annual and Clinical Conventions.
- AMA MEMBERSHIP BENEFITS AND SERVICES ARE THE MOST EXTENSIVE OF ANY PROFESSIONAL ORGANIZATION, AND NEW ONES ARE CONTINUALLY BEING ADDED.

Here are some of the things that HAVE happened because the AMA represented your interests:

- Modification of the Keogh law to allow increased annual contributions to retirement plans of 15% of earned income or $7,500, whichever is less
- Universal health insurance claim form
- Broader ambulatory insurance coverage
- Model state legislation to safeguard medical information
- AHA acceptance of the concept that medical staffs should be represented on hospital boards
- Due process guarantees for physician hospital privileges
- Reduction of third party interference in physician-patient relationship
- *Physician-Hospital Relations*—AMA report which establishes policy and procedure for protecting important medical staff and physician rights

Here is some of the legislation the AMA has either sponsored or supported to improve health care in America:

Drafted and Sponsored

- National Health Insurance (Medicredit)
- Nationwide System of Emergency Medical Services
- Amending Antitrust Laws Regarding Blood Banks
- Improved Rural Health Care
- Better Drug Labeling

Supported

- Health Manpower Training—maximum funding
- Nurse Training—maximum funding
- Public Health Training
- Indian Health Care Improvement Act.
- National Health Service Corps
- Extension of the Maternal and Child Care Health Program.
- Community Mental Health Centers
- Drug Abuse Education Act
- Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation
- Communicable Disease Control Act
- Allied Health Training

Here are some of the innovative and on-going programs the AMA has developed and activities it pursues to improve health care in America:

- Model school health screening programs
- Model emergency medical services programs for the nation's airports
- Pilot nutritional education programs for the poor
- Model drug abuse programs for local communities
- Innovative rural health care delivery systems
- New approaches to health care delivery for the poor
- Exploration of environmental, occupational health problems and development of solutions.
- Distribution of over 10 million pieces of health education literature to the public, schools, and public health agencies
- Investigation and exposure of quacks and quack products
- Guidelines for comprehensive emergency medical care systems, training of ambulance personnel, and categorization of hospital emergency care capabilities

Here are some of the ways the AMA works on behalf of the profession to assure quality medical education and care:

- As a member of CCME, the AMA participates in accreditation of medical schools and review and certification of internship and residency programs
- As a member of JCAH, the AMA shares responsibility for accreditation of hospitals and other health care facilities and services
- Accredits schools and training programs for allied health personnel
- Assists in the development of continuing education study programs in every branch of medicine. Instituted the Physician Recognition Award
- Participated in development of various review committees of medical staffs
- Guardian of medical ethics
- Sponsors or co-sponsors more than 1,000 meetings and medical and health study sessions each year

Recent Study of Allied Medical Organizations' Dues Increases

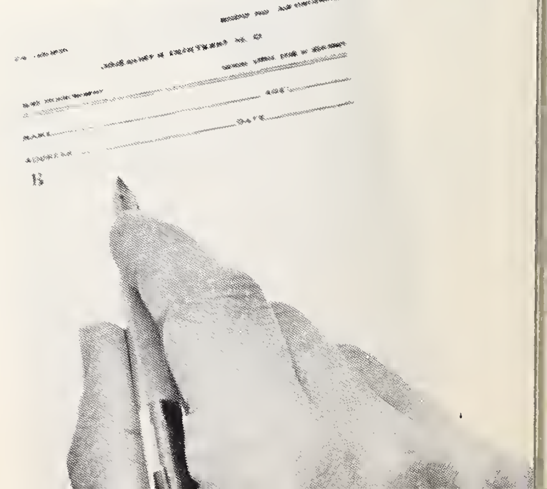
(1) Thirty-seven state medical associations have increased their dues within the past two years. These dues now average $143. Seven state medical associations have a dues of $200 or more. Thirty-eight state medical associations have a dues of $110 or more.

(2) Of the three hundred fifty staffed county medical societies, over 65% have increased their dues in the past three years.

(3) Fourteen of the twenty-seven national specialty societies have increased their dues within the past two years.

The American Medical Association obtains approximately 53% of its revenue from physicians' dues. AMA has held the line on dues increases for almost five years.

Bioequivalence



Poison ivy and other severe allergic states intractable to adequate trials of conventional treatment will often respond to a short, intensive, adjunctive course of Medrol. Medrol Dosepak is designed to provide a tapered, six-day course of methylprednisolone tablets.

On occasion, a six-day course of Medrol therapy may not be sufficient and therapy may need to be extended. If there is continued contact with the sensitizing agent, corticosteroids will not completely suppress the inflammatory response. A further caution: If lesions become infected during Medrol therapy, it should be remembered that steroids may decrease resistance to infection and hinder the body's ability to localize an infection.

MEDROL COMPRESSED TABLETS—2, 4 & 16 MG
(METHYLPREDNISOLONE TABLETS, N.F., UPJOHN)

DESCRIPTION AND ACTIONS: Medrol (methylprednisolone) is a synthetic glucocorticoid with potent anti-inflammatory effects. It is readily absorbed from the GI tract. Glucocorticoids cause profound and varied metabolic effects and modify the body's immune responses to diverse stimuli.

INDICATIONS: 1. **Endocrine Disorders:** Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy, mineralocorticoid supplementation is of particular importance). Congenital adrenal hyperplasia; nonsuppurative thyroiditis; hypercalcemia associated with cancer. 2. **Rheumatic Disorders:** As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis; rheumatoid arthritis (selected cases may require low-dose maintenance therapy); ankylosing spondylitis; acute and subacute bursitis; acute nonspecific tenosynovitis; acute gouty arthritis. 3. **Collagen Diseases:** During an exacerbation or as maintenance therapy in selected cases of—Systemic lupus erythematosus; acute rheumatic carditis. 4. **Dermatologic Diseases:** Pemphigus; bullous dermatitis herpetiformis; severe erythema multiforme (Stevens-Johnson syndrome); exfoliative dermatitis; mycosis fungoides; severe psoriasis. 5. **Allergic States:** Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment: Seasonal or perennial allergic rhinitis; bronchial asthma; contact dermatitis; atopic dermatitis; serum sickness. 6. **Ophthalmic Diseases:** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as—allergic corneal marginal ulcers; herpes zoster ophthalmicus; anterior segment inflammation; diffuse posterior uveitis and choroiditis; sympathetic ophthalmia; allergic conjunctivitis; keratitis; chorioretinitis; optic neuritis; iritis and iridocyclitis. 7. **Respiratory Diseases:** Symptomatic sarcoidosis; Loeffler's syndrome not manageable by other means; berylliosis; fulminating or disseminated pulmonary tuberculosis when concurrently accompanied by appropriate antituberculous chemotherapy. 8. **Hematologic Disorders:** Idiopathic and secondary thrombocytopenia in adults; acquired (autoimmune) hemolytic anemia; erythroblastopenia (RBC anemia); congenital (erythroid) hyperplastic anemia. 9. **Neoplastic Diseases:** For palliative management of: leukemias and lymphomas in adults; acute leukemia of childhood. 10. **Edematous States:** To induce a diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus. 11. **Miscellaneous:** Tuberculous meningitis with subarachnoid block or impending block when concurrently accompanied by appropriate antituberculous chemotherapy. Systemic dermatomyositis (polymyositis).

CONTRAINDICATIONS: Systemic fungal infections.

WARNINGS: In patients on corticosteroid therapy subjected to unusual stress, increased dosage of rapidly acting corticosteroids before, during, and after the stressful situation is indicated.

Corticosteroids may mask some signs of infection and new infections may appear during their use. There may also be decreased resistance and inability to localize infection. Prolonged use may enhance the establishment of secondary ocular infections due to fungi or viruses.

Since adequate human reproductive studies have not been done, the use in pregnancy, nursing mothers or women of childbearing potential requires that the possible benefits be weighed against the potential hazards to the mother and the embryo or fetus. Infants should be observed for signs of hypoadrenalism.

Average and large doses of hydrocortisone or cortisone can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when used in large doses. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.

While on corticosteroid therapy, patients should not be vaccinated against smallpox. Other immunization procedures should not be undertaken in patients who are on corticosteroids, especially on high dose, because of possible hazards of neurological complications and a lack of antibody response.

The use of corticosteroids in active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the management of the disease in conjunction with an appropriate antituberculous regimen.

If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary as reactivation of the disease may occur. During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.

PRECAUTIONS: Hormone therapy is an adjunct to, and not a replacement for, conventional therapy.

Dosage should be individualized according to the severity of the disease and the response of the patient. As soon as a satisfactory clinical response is obtained, the daily dose should be reduced, either to termination of treatment or to the minimal effective maintenance dose level. The lowest possible dose should be used and when reduction in dosage is possible, the reduction should be gradual if the drug has been administered for more than a few days. If a period of spontaneous remission occurs in a chronic condition, treatment should be discontinued.

Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.

There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with cirrhosis.

Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation.

Psychic derangements may appear or existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.

Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia.

Steroids should be used with caution in nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess or other pyogenic infection; diverticulitis; fresh intestinal anastomoses; active or latent peptic ulcer; renal insufficiency; hypertension; osteoporosis; and myasthenia gravis.

Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed.

Blood pressure, body weight, routine laboratory studies, including 2-hour postprandial blood glucose and serum potassium, and a chest X-ray should be obtained at regular intervals during prolonged therapy. Upper GI X-rays are desirable in patients with known or suspected peptic ulcer disease.

ADVERSE REACTIONS: Fluid and Electrolyte Disturbances. Sodium retention; fluid retention; congestive heart failure in susceptible patients; potassium loss; hypokalemic alkalosis; hypertension. **Musculoskeletal.** Muscle weakness; steroid myopathy; loss of muscle mass; osteoporosis; vertebral compression fractures; aseptic necrosis of femoral and humeral heads; pathologic fracture of long bones. **Gastrointestinal.** Peptic ulcer with possible perforation and hemorrhage; pancreatitis; abdominal distention; ulcerative esophagitis. **Dermatologic.** Impaired wound healing; thin fragile skin; petechiae and ecchymoses; facial erythema; increased sweating. May suppress reactions to skin tests. **Neurological.** Increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment. Convulsions; vertigo; headache. **Endocrine.** Development of Cushingoid state; suppression of growth in children; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness; menstrual irregularities; decreased carbohydrate tolerance; manifestations of latent diabetes mellitus; increased requirements for insulin or oral hypoglycemic agents in diabetics. **Ophthalmic.** Posterior subcapsular cataracts; increased intraocular pressure; glaucoma; exophthalmos. **Metabolic.** Negative nitrogen balance due to protein catabolism.

DOSAGE AND ADMINISTRATION: The initial dosage may vary from 4 to 48 mg per day. **Requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient.** The proper maintenance dosage should be determined by decreasing the initial dosage in small decrements at appropriate time intervals until the lowest dosage which will maintain an adequate clinical response is reached. If after long-term therapy the drug is to be stopped, it is recommended that it be withdrawn gradually rather than abruptly.

ALTERNATE-DAY THERAPY (ADT): ADT is a corticosteroid dosing regimen in which twice the usual daily dose of corticoid is administered every other morning. The purpose of this mode of therapy is to provide the patient requiring long-term pharmacologic dose treatment with the beneficial effects of corticoids while minimizing certain undesirable effects including pituitary-adrenal suppression, the Cushingoid state, corticoid withdrawal symptoms, and growth suppression in children.

Medrol (methylprednisolone) or other short-acting (producing adrenocortical suppression for 1¼ to 1½ days following a single dose) corticoids are recommended for ADT. Complete control of symptoms will not be possible in all patients. When considering this mode of therapy, keep in mind the basic principles and indications for corticosteroid therapy. The benefits of ADT should not encourage the indiscriminate use of steroids.

SUPPLIED: 2 mg—in bottles of 30 and 100 scored tablets; **4 mg**—in bottles of 30, 100 and 500 scored tablets and in 21 scored tablet Dosepak™ , **16 mg**—in bottles of 50 scored tablets and in 14 scored tablet ADT Pak® (formerly Alternate Daypak®).

MED B-8-S (MAG)

FOR ADDITIONAL PRODUCT INFORMATION, CONSULT THE PACKAGE INSERT OR SEE YOUR UPJOHN REPRESENTATIVE. J-3748-4 July, 1974

Short-term, adjunctive,
corticosteroid therapy
Medrol® 4 mg Dosepak™
(methylprednisolone)

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Continued from page 392

Welcome, New Members

FAIRFIELD COUNTY

Gail F. Alexander, Greenwich
Marcelle Bernard, Norwalk
Joel E. Brook, Ridgefield
William J. Caragol, Old Greenwich
Thomas R. Casey, Fairfield
Jeremy Chess, Norwalk
Terence S. Fitzgerald, Stamford
Ervin E. Hanson, Greenwich
John R. Iacovino, Norwalk
Walter Lucia, Bridgeport
Robert S. Moskowitz, Norwalk
Sukh S. R. Nehta, Stamford
Roland M. Nesi, Brookfield
Richard L. O'Connell, Stamford
Herman D. Pocock, Fairfield
Chan-Kook Rha, Stamford
Elizabeth R. Rosenthal, Danbury
Perry Seamonds, Greenwich
Suvarna M. Shah, South Norwalk
Stanley R. Skolnick, Darien
Robert L. Stubblefield, New Canaan
Carl Zelson, Ridgefield

HARTFORD COUNTY

Srimathi Balakrishna, Glastonbury
William S. Blomquist, Granby
George P. Bloom, Hartford
John W. Cavo, Jr., New Britain
Conrad D. Collins, Plainville
Joel Deutsch, Hartford
Richard A. Fahy, Hartford
Joseph J. Farraye, Avon
Patrick J. Fazzari, Newington
Ernst Fenelon, Hartford
J. Robert Galvin, Manchester
Thomas M. Graf, Hartford
Robert D. Greenberg, Vernon
J. Kent Hewitt, Hartford
R. L. Kurukulasuriya, Manchester
Fred Mantel, Hartford
Vance H. Marchbanks, Jr., Hartford
Sheldon Nova, Hartford
Lewis P. Parker, Hartford
Walter Paslawski, Hartford
Burt D. Pina, East Hartford
Gary E. Russolillo, Hartford
Michael J. Ryan, Jr., Hartford
Shue W. Wong, Bristol
Constantine Zariphes, Jr., Manchester

Balanced high potency vitamin B-complex and 500 mg vitamin C

Virtually no odor or aftertaste

Low priced Rx formula

Rx
Berocca Tablets
#100
Sig: 1 Tab
B.I.D.

Please see complete product information, a summary of which follows:

Each Berocca Tablet contains:
Thiamine mononitrate (Vitamin B_1) 15 mg
Riboflavin (Vitamin B_2) . . . . 15 mg
Pyridoxine HCl (Vitamin B_6) . . . . 5 mg
Niacinamide . . . . 100 mg
Calcium pantothenate . . . . 20 mg
Cyanocobalamin (Vitamin B_{12}) . . 5 mcg
Folic acid . . . . 0.5 mg
Ascorbic acid (Vitamin C) . . . . . . 500 mg

Indications: Nutritional supplementation in conditions in which water-soluble vitamins are required prophylactically or therapeutically.

Warning: Not intended for treatment of pernicious anemia or other primary or secondary anemias. Neurologic involvement may develop or progress, despite temporary remission of anemia, in patients with pernicious anemia who receive more than 0.1 mg of folic acid per day and who are inadequately treated with vitamin B_{12}.

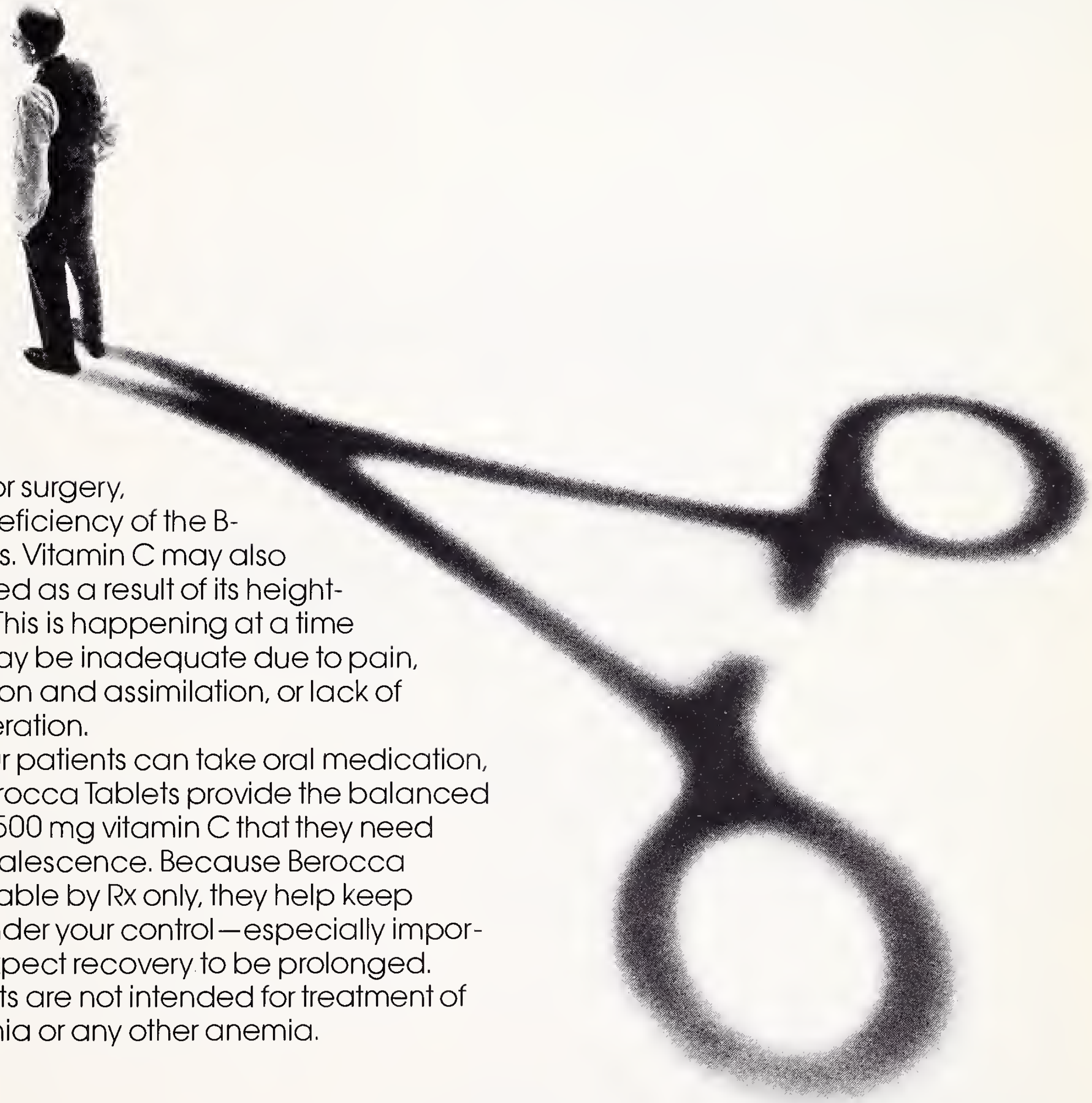
Dosage: 1 or 2 tablets daily, as indicated by clinical need.

Available: In bottles of 100 and 500.

ROCHE LABORATORIES
Division of Hoffmann-La Roche Inc.
Nutley, New Jersey 07110

ROCHE

The silent disorder: Vitamin deficiency in the postoperative patient



Silent—but often present in subclinical form.

Following major surgery, there is often a deficiency of the B-complex vitamins. Vitamin C may also become depleted as a result of its heightened utilization. This is happening at a time when nutrition may be inadequate due to pain, impaired digestion and assimilation, or lack of mealtime cooperation.

As soon as your patients can take oral medication, high potency Berocca Tablets provide the balanced B-complex and 500 mg vitamin C that they need for general convalescence. Because Berocca Tablets are available by Rx only, they help keep vitamin intake under your control—especially important when you expect recovery to be prolonged.

Berocca Tablets are not intended for treatment of pernicious anemia or any other anemia.

To overcome the B and C deficit

BEROCCA® IS THERAPY

TABLETS Balanced high potency vitamin B-complex and **500 mg vitamin C.** Virtually no odor or aftertaste. Low priced Rx formula.

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FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, Conn. 06511
Telephone 865-0587

Francis G. Sweeney
Assistant Executive Director
Public Affairs

William R. Richards, M.D.
Executive Director
Josephine P. Lindquist
Associate Executive Director

Leonard R. Tomat
Assistant Executive Director
Scientific Activities

Summary of Actions
Council Meeting
Thursday, April 17, 1975

I. Attendance

Present in addition to the Chairman, Dr. D.A. Grendon, and the Vice Chairman, Dr. C.W. Johnson, were: Drs. Root, Jr., VanSyckle, Spitz, Backhus, Brandon, Nolan, Gardner, Fabro, Bradley, Hess, Cramer, Granoff, Rubinow, Ragland, Jr., James, Freedman, Krinsky, Roch, Beck, McGarry, Canzonetti, Harkins, Mendillo, Eslami, Sonnen and Klare.

Also present were: Mrs. Lindquist, Mr. Tomat, Mr. Sweeney, Mr. Olson (FCMA), Dr. Robinson (incoming Associate Councilor, HCMA) and Dr. Richards.

Absent were: Drs. Kamens, Dambeck, Sadowski and Magram.

II. Routine Business

Approval of Minutes

As published and distributed, it was VOTED to approve the minutes of the meeting of March 19, 1975.

Life Memberships

It was VOTED to approve applications for Life Membership received from eligible Active Members as follows:

Louis J. Aiello, 394 West Avenue, Norwalk
Donald M. Biehn, 47 Parkway, Fairfield
Joseph P. Connolly, 193 Davenport Drive, Stamford
Paul P. Duzmati, 1904 Boston Avenue, Bridgeport
Francis X. Foley, 2660 Main Street, Bridgeport
George H. Gerow, 34 Imperial Avenue, Westport
George W. Hebard, P.O. Box 758, New Canaan
Arthur Koffler, 39 Glenbrook Road, Stamford
Salvatore LaCorte, 90 Wyndover Lane, Stamford
Samuel H. Levy, 3007 Main Street, Stratford
Kurt A. Oster, 881 Lafayette Street, Bridgeport
Roy C. Robison, 95 Morgan Street, Stamford
Maynard C. Wheeler, Box 355, Southbury
Joseph C. Woodward, 358 Montauk Avenue, New London

Date of Next Meeting

The incoming President, Guy W. VanSyckle, announced that the next (organizational for 1975-76) meeting of the Council will be held on Wednesday, May 21, 1975.

III. Old, New and Special Business

Election of Student Members

It was VOTED to elect to Student Membership four Connecticut residents who are enrolled as students in U.S. medical schools as follows:

Judson R. Belmonte, 109 Webster Ct., Newington, Conn.
University of Connecticut—Class of 1978
Pre-Med: West Point
Parent: William C. Belmonte

Richard P. Creagan, 4F Staunton Rd., Farmington, Conn.
University of Connecticut—Class of 1978
Pre-Med: Yale, Clark, WPI, Harvard, SCSC & Un. New Haven
Parent: Paul T. Creagan, Jr.

Londe A. Richardson, 128 Thames St., Groton, Conn.
Yale University—Class of 1978
Pre-Med: Connecticut College
Parent: Charles M. Richardson

Robert D. Small, 85 Blanchard Rd., Easton, Conn.
New York Medical College—Class of 1977
Pre-Med: Tufts University
Parent: Alan R. Small, M.D.

Communication re CSMS "Medical Cooperative"

Received from a Milford member of the Society was a letter which proposed that the Council consider establishing a "medical cooperative" or "surgical supply co-op" for members as a function of the Society. Following due discussion, it was VOTED to inform the member that the Council is not in favor of establishing a mechanism for cooperative buying of durable goods under the auspices of the Society. Note was made that such co-ops for physicians are available under for-profit auspices.

Component Associations' Actions on "Mandatory CME"

It was VOTED to receive as information one written and several verbal reports of County Medical Associations' attitudes toward mandatory continuing medical education as a condition of Association membership. The report in writing was received from the Board of Governors of the New Haven Association and expressed strong favor for *"voluntary* continuing medical education for all physicians." The verbal reports were not definitive and, therefore, are not recorded in these minutes.

In a related action, the Council VOTED to direct the Chairman to include in his supplementary "Report of the Council" to the House of Delegates on April 30 the following recommendation of the Council: That the question of mandatory continuing medical education (CME) as a condition of membership in the component County Medical Associations be referred back to the Committee on CME for further study of the need for such a contingency of membership, and, if found needed, for the development of a detailed CME program the implementation of which will satisfy such need.

Resolution re "Health Service Areas Conforming to PSRO Areas"

After approving several major amendments to a subject resolution submitted by James H. Root, Waterbury, it was VOTED to adopt the amended resolution as follows:

RESOLVED: That the Council of the Connecticut State Medical Society express strong favor for the designation of four health service areas in the implementation of P.L. 93-641 in Connecticut which will be identical with the four PSRO areas which have already been established in the state with the approval of the Secretary of HEW; and be it further

RESOLVED: That the above resolve be transmitted to the key people, at state and national levels, who have the responsibility for implementing P.L. 93-641 (The Health Planning and Resources Development Act of 1975), including Governor Grasso and Connecticut's two senators and six representatives who serve in the U.S. Congress.

Report—CSMS Representative on Commission on Hospitals and Health Care

It was VOTED to accept for filing a compilation of correspondence, etc., gathered and submitted by Sidney L. Cramer, Hartford, CSMS representative on the subject Commission. The principal matter to which the various elements of the compilation referred was the question of the cost to patients of the rapidly increasing number of physicians employed full-time by hospitals, which, in toto, Dr. Cramer estimates to be in the neighborhood of $6 million in salaries and fringe benefits in Connecticut at the present time. It was further VOTED to accept Dr. Cramer's report with thanks and commendation.

Acceptance of Check from Merck, Sharp and Dohme Pharmaceutical Co.

On behalf of the Society, the Council VOTED to acknowledge, and accept with thanks, a check in the amount of $2,000 received from the Merck, Sharp and Dohme Company to defray the costs of taping "radio spot" announcements on health subjects which the Committee on Public Relations is planning as a pilot program series to be offered to local radio stations throughout the state for broadcast on public service time.

Reports—Committee on Public Health

It was VOTED to accept for filing a report submitted by the Committee on Public Health. It was further VOTED to approve a recommendation contained in the report that the Council endorse a document published by the Connecticut Child Abuse Committee titled: "Position Paper on Protection of Children and Child Abuse" and to notify the Department of Children and Youth Services of such endorsement. The Committee's report indicated that the subject document already has the approval of the Connecticut Child Welfare Association and the Connecticut Chapter of the American Academy of Pediatrics.

Update Report on Connecticut Ambulatory Care Study

The Council was joined by Frederick W. Weber, Jr., CACS Principal Investigatior, and Daniel Hamaty, CACS Project Director, who jointly presented a running account of the Study's progress and problems since it was first conceived in mid-year, 1972. In brief, it appears that enough data has been collected on which to base a valid report. The cost study, which was to parallel the quality study in various solo and group settings was abandoned because (a) a study method could not be agreed upon by the participating organizations, and (b), the funding agency would not provide money with which to launch a separate study of costs. The collected data is now being prepared for computer analysis. With the supplementary grant of $25,000 recently given the CACS by the Connecticut Regional Medical Program and other financial contributions made or to be made by the UConn and Yale medical schools and perhaps other agencies, it is anticipated that the Study can continue to function until August of the current year. Whether the report on the Study and its findings can be completed by August will depend on how rapidly the necessary processing of the data can be achieved, how much time the writing of the report requires and how much money is made available by the various sources tapped for financial support.

Following protracted discussion of the information furnished by Drs. Weber and Hamaty, directly and in response to questions, it was VOTED to accept with thanks and commendation the report which they had presented jointly.

Proposal of "Audio Transcripts, Limited"

It was VOTED to approve a proposal of the subject transcribing company to tape the proceedings of the Society's Scientific Assembly, to be held in Hartford on Thursday, May 1, and to make available to interested individuals or groups one-hour cassettes of such proceedings at a cost of $6.00 each plus shipping charges, if any. The project will be undertaken at no cost to the Society and releases will be obtained from all speakers whose presentations are taped.

Reports on Activities of "Important Outside Agencies"

(a) *Executive Committee, Connecticut Regional Medical Program:* Orvan W. Hess, New Haven, reported that the CRMP Executive Committee had voted to approve a "two health service area" approach to the implementation of P.L. 93-641 in Connecticut, and that he and J. Alfred Fabro, Torrington, as CSMS-designates, had abstained from voting on the two-area approach. Dr. Hess displayed a map prepared by CRMP which appeared to indicate that each of the two proposed areas would relate to one of the State's two medical schools. Dr. Hess' report was received as information.

(b) *Connecticut Cancer Center at Yale:* E. Tremain Bradley, Norwalk, reported verbally on several matters relating to cancer programs. He noted that the brochure titled "Follow-Up of Cancer" was being widely and enthusiastically accepted and that a second printing had become necessary in order to satisfy the large number of requests for copies that has been received. On his recommendation, the Council VOTED to "favor the concept that the Cancer Center Consortium be a free-standing organization, whether incorporated or unincorporated." Dr. Bradley also brought to the Council's attention several pieces of incidental information about malpractice.

Report—Delegate to N.E. Council

It was VOTED to accept for information a report on the proceedings of the 4/5/75 Boston meeting of the Council of New England State Medical Societies which was submitted to the CSMS Council by William M. Shepard, Putnam, one of the Society's six delegates to the CNESMS. Dr. Shepard's report indicated that the problems of malpractice suits and professional liability insurance are common to the six New England states.

Communication—Committee to Study Perinatal Morbidity and Mortality

It was VOTED to accept for filing a communication from the subject Committee in reference to a bill which has been before the General Assembly concerning human experimentation and, apparently, has been withdrawn by the Committee on Public Health and Safety after having initially been given a favorable report by that Committee. The letter, signed by William E. Lattanzi, CSMS Committee chairman, states: "All legislative bills that would restrict research in the perinatal areas should be directly examined for their import and possible consequences to the development of knowledge and progress in this area. The Committee feels it is very important that the abortion issue be separated from the research issue." The Society's Committee on Legislation had earlier taken a "no position" position on the skeleton bill on which the final bill was based. It was further VOTED to refer the communication to the Committee on State Legislation as information and for future reference.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on April 17, 1975. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

The University of Connecticut Health Center Drug Information Service

What is the current status of pemoline?

Pemoline is a CNS stimulant recently released by the FDA under the brand name Cylert (Abbott). Chemically it is 2-amino-5-phenyl-2-oxazolin-4-one and is structurally dissimilar from the amphetamines and methylphenidate.

The pharmacologic activity of pemoline is similar to that of other stimulants but the manufacturer claims fewer sympathomimetic effects (tachycardia, elevated BP). Although the specific mechanism of action has not been identified, pemoline does increase the rate of synthesis of dopamine in the rat brain.

Pemoline has been approved for treating children with minimal brain dysfunction, usually in conjunction with other remedial measures. It is administered as a single oral dose each morning. The recommended starting dose is 37.5 mg per day. This daily dosage should be gradually increased at one week intervals using increments of 18.75 mg until the desired clinical response is obtained. The mean daily effective dose ranges from 56.25 to 75 mg per day. The maximum recommended daily dose of pemoline is 112.5 mg. Using the recommended schedule of dosage titration, significant benefit may not be evident until the third or fourth week of drug administration. Drug administration should be interrupted occasionally to determine if behavioral symptoms sufficient to require continuing therapy recur.

The most frequently reported adverse reaction is insomnia. Insomnia has been observed prior to optimum therapeutic response and in the majority of cases was transient in nature or responded to dosage reduction. Anorexia with weight loss during the first few weeks of therapy has also been reported. With continuing therapy, a return to a normal weight curve usually occurred within 3 to 6 months. Other adverse reactions reported include GI upset, skin rash, irritability, mild depression, nausea, dizziness, headache, drowsiness, and hallucinations. Mild adverse reactions appearing early in treatment often remit with continuing therapy. If adverse reactions are of a significant or protracted nature, dosage reduction or discontinuation should be considered.

It is not recommended for children under 6 yrs. of age since safety and efficacy in this age group have not yet been established. Since pemoline and its metabolites are excreted primarily by the kidneys, caution should be observed in administering the drug to children with significantly impaired renal function. Sufficient data on safety and efficacy of administration for periods beyond 2 yrs. duration in children with minimal brain dysfunction are not yet available. Although a definite causal relationship has not been established, some temporary suppression of predicted growth pattern (i.e. weight and/or height) has been reported with the long-term use of stimulants in children. Therefore, patients requiring long-term therapy should be carefully monitored.

Delayed hypersensitivity reactions involving the liver have been reported in 1-2% of the patients receiving pemoline usually after several months of therapy. No clinical symptomatology has been observed, but mild to moderate increases in transaminase (SGOT and SGPT) levels have occurred in these cases. These effects appear to be completely reversible when drug treatment is discontinued. Transaminase levels should be determined periodically during therapy with pemoline to detect any such reactions.

Pemoline is available as Cylert (Abbott) in 18.75 mg (.07 ea.), 37.5 mg (.11 ea.), and 75 mg (.19 ea.) tablets.

Supported by the School of Pharmacy and Department of Pharmacy, UConn Health Center.

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiry of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511, (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine*.

ALLIED HEALTH

Physician's Assistant: Graduate of Yale's PA Program. Certified 12/74 by National Board of Medical Examiners for Physician's Assistants. Married, three children. Desires solo or group setting with physician or physicians having a busy practice. Write or call CSMS for resume.

Physician's Assistant: Available in August 1975. Prefers area of Family Practice, Emergency Room, Pediatrics or Surgery. Married, three children. 29 years old. Write Mr. M. Litzman, 888 Montgomery Street, Brooklyn, N.Y. 11213.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

Emergency Room Physician: Full-service community hospital in suburban setting, with university medical and research centers nearby. Competitive salary for career-oriented individual. Send resume to: Administrator, Meriden-Wallingford Hospital, 181 Cook Ave., Meriden, CT. 06450.

Ob/Gyn: To join group in Waterbury area. Send resume to P.D., M.D., c/o SCMS.

Internal Medicine or Pediatrician or Family Practitioner preferred as Medical Director for Independent Co-ordinate Preparatory School. 890 students. 21 bed infirmary. Experienced nursing staff. Year-round housing on attractive campus. Salary and numerous fringe benefits. Incumbent retires no later than June 1976. Contact W. S. Norton, M.D., Choate Rosemary Hall, Wallingford, CT. 06492.

Director of Student Health/College Physician: Connecticut College in New London. 1,600 co-ed campus. Associate physician and staff of 8 cover 22 bed infirmary. Experience in managing physicians, nurses and personnel in comprehensive health delivery program. Salary negotiable; liberal fringe benefits. One month summer vacation. July 1, 1975. Dean Jewel Plummer Cobb, Connecticut College, New London, Ct. 06320.

Family Practice: One or two partners needed in Connecticut shore community. Convenient to New London, Middletown and New Haven. Busy summer season. Forward resume to L.M.A. c/o CSMS.

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

(If no name is listed, contact the Physicians Placement Service)

Anesthesiology: Available immediately. Group practice. Board eligible. Completing residency at St. Mary's Hospital in Brooklyn. 34 years of age. Josefina C. Tan, M.D., 14 Branding Iron Lane, Glen Cove, N.Y.

Anesthesiology: Board certified. Presently in practice. Connecticut license through endorsement. Trained in Canada. 37 years old, married. Jong Chill Sun, M.D., 5100 High Bridge Street, No. 14C, Fayetteville, N.Y. 13066.

Anesthesiology: Board certified. Presently in practice. 32 years old. Married. Pennsylvania license. Available now. Roger G. Bucs, M.D., 396 Yorktown Rd., Hershey, PA. 17033.

Anesthesiology: FLEX. Part I for certification completed. Available July 1975. 31 years old. Married. Yogaratnam Gunaratnan, M.D., 14 Second Street, Apt. 4, Hackensack, N.J. 07601.

Anesthesiology: Available August 1975. FLEX. Board eligible. 31 years old. 3½ years of anesthesia and ICU. Contact: S. Kahn, M.D., 212-650-7475. Mount Sinai Hospital, N.Y.

Dermatology: Wishes to relocate in Connecticut from New York City. 58 years old. Presently in private practice. 14 years in the U.S. Navy. Connecticut license. Write or call CSMS for resume.

General Practice: Connecticut License. Experience in ambulatory care. Graduate of Albany Medical College. Medium or small community. Group, associate or institutional practice. Available summer of 1975. Resume available at CSMS.

Internal Medicine-Cardiology: Available July 1975. Board certified. FLEX. Group practice or institutional position. 30 years old. Samuel P. Kumar, M.D., 264-31 Langston Ave., Glen Oaks, N.Y. 11004.

Internal Medicine: (Pulmonary Diseases). Available July 1975. 31 years old. Married. Completing fellowship at University of Cincinnati. FLEX. Harris Musafer, M.D., 2910 Scioto Street, "Sawyer Hall," Cincinnati, O. 45219.

Internal Medicine: (Gastroenterologist) Board eligible. ABIM. FLEX. 39 years old. Married. Desires practice in medium sized community or institutional position. Teaching experience. Available July 1975. Presently in practice in New Jersey. Kedar N. Kapoor, M.D., 1824 Country Club Drive, Cherry Hill, N.J. 08003.

Neurology: Available July 1975. Completing training at VA Hospital and Jefferson Medical College. 35 years old. Married. Board eligible. Prefers institutional or associate type practice. Sheikh Muhammed Sadiq, M.D., Box 413, V.A. Hospital, Coatesville, Pa. 19320.

Ob/Gyn: Available July 1975. FLEX. Connecticut license by endorsement. Trained at Royal College of OB-GYN in London, U.K., M.J. Shah, M.D., No. 24-3000 Staunton Avenue, Charleston, W.V. 25304.

Ophthalmology: Board eligible. Presently available. 30 years old. Particularly interested in southern Connecticut. Group or associate practice. Daniel Rosenbaum, M.D., 88 Atlantic Avenue, Brooklyn, N.Y. 11201.

Orthopaedics: Board certified. Presently in practice. 32 years old. Connecticut license. Available July 1975. Fordham and N.Y. Medical College. Internship and residency at Greenwich Hospital, C.J.R., M.D., c/o CSMS.

Orthopaedics: Desires western Connecticut. Presently in practice. 35 years old. Married. Solo, group or associate practice. Columbia-Presbyterian trained. Diplomate of the N.B.M.E., Lawrence A. Lefkowitz, M.D., 1020 NE 178 Terrace, No. Miami Beach, FL. 33162.

Pediatrics: Interested in Neurology and Neonatology. Board eligible. 33 years old. Married. Georgetown Med. and Children's Hospital in Cincinnati. Available July 1975. Group or associate practice. J.A. Flanagan, M.D., 2873 Fairhill Dr., Cincinnati, O. 45239.

Pediatrics: Board eligible. Available July 1975. 28 years old. Group or associate practice. University of Rochester and Columbia. Available immediately. Jesse M. Mintz, M.D., 1187 Briscoe Ct., St. Louis, MO. 63132.

Pediatrics: Board eligible. Pediatric Hematology and Oncology with General Pediatrics. 47 years old. Massachusetts and California license. Write CSMS.

Pediatrics: Connecticut license. Available July 1975. Presently completing fellowship at N.Y. Hospital—Cornell Medical Center. FLEX. Board eligible. Interested in group or associate practice or institutional position. Bertram N. Dias, M.D., 40 Prospect Avenue, Norwalk, Ct. 06850. 203-866-9915.

Psychiatry: Desires situation within commuting distance from N.Y.C. Presently in practice. Residency at University of Missouri-Columbia and St. Louis. Pawan Chadha, M.D., 118 East Oakland Street, Monticello, Ark. 71655.

Psychiatry: Desires part-time position to combine with private practice. Available October 1975. 34 years old. Married. Presently in Air Force. Trained at Yale Child Study Center. Board eligible. Glen L. Bohlke, M.D., 7026 Madelynne Way, Anchorage, AK. 99504.

Surgery: Part I—American Board of Surgery. Available August 1975. RPI and SUNY Downstate Brooklyn, N.Y. trained. Presently in Navy. Wyman W. Chu, M.D., 825 Bayshore Dr., Apt. 1204, Pennsacola, FL. 32512.

Surgery: Plastic: Board eligible. 36 years old. FLEX. PA. license. Available July 1975. American internship and residency. Roberto Montoya, M.D., 410 Cessna Ave., Charleston, S.C. 29407.

Surgery: General: Specializing in surgery of the hand. Completing fellowship. Certified by American Board of Surgery. Available immediately. Lewis Chamoy, M.D., 1139 S. Monaco Pkwy., Denver, CO. 80222.

In Memoriam

Finley, George C., Tufts Medical School, 1924. Dr. Finley was a practicing surgeon in the Hartford area since 1924. He was a former attending surgical chief at St. Francis and University-McCook Hospitals for many years, and was past president of the Surgical-Medical staff at St. Francis Hospital and a consulting surgeon to the state Department of Health. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Finley died March 12, 1975, at the age of 74.

Isenman, Robert, Tufts University, 1930. Dr. Isenman was a general practitioner in the Fairfield area since 1932. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Isenman died February 26, 1975, at the age of 71.

Kunkel, F. Earle, Yale Medical School, 1926. Dr. Kunkel was a dermatologist in the Hartford area since 1926. He had been appointed to serve on the medical staff of McCook Memorial Hospital, New Britain General Hospital, Middlesex Memorial Hospital, Windham County Memorial Hospital and Hartford Hospital. He was a member of the Hartford County Medical Association, The Connecticut State Medical Society and the American Medical Association. Dr. Kunkel died March 14, 1975, at the age of 77.

Monahan, David T., Yale School of Medicine, 1933. Dr. Monahan was a practicing surgeon in the Fairfield area since 1936. He was a lieutenant colonel in the U.S. Army during World War II and was awarded the bronze star and four battle stars. He was then chief of surgery at Lowell General Hospital in Lowell, Mass. He returned to Bridgeport in 1946 and served as assistant surgeon at Bridgeport Hospital, and was later promoted to associate and senior attending surgeon. In his private practice, he specialized in gynecology. He was a member of the Connecticut State Medical Society and the Fairfield County Medical Association. He served as Editor of *Connecticut Medicine* from June through October, 1958. Dr. Monahan died March 27, 1975 at the age of 69.

Polito, Frank L., Yale Medical School, 1921. Dr. Polito was a former chief of surgery at Charlotte Hungerford Hospital and a former president of the Litchfield County Medical Association. He was also a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Polito died at Fort Lauderdale, Fla., April 12, 1975 at the age of 79.

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